

AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 2473
OFFERED BY MR. TAUZIN

Strike all after the enacting clause and insert the
following:

1 **SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SE-**
2 **CURITY ACT; REFERENCES TO BIPA AND**
3 **SECRETARY; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the “Medi-
5 care Prescription Drug and Modernization Act of 2003”.

6 (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as
7 otherwise specifically provided, whenever in this Act an amend-
8 ment is expressed in terms of an amendment to or repeal of
9 a section or other provision, the reference shall be considered
10 to be made to that section or other provision of the Social Se-
11 curity Act.

12 (c) BIPA; SECRETARY.—In this Act:

13 (1) BIPA.—The term “BIPA” means the Medicare,
14 Medicaid, and SCHIP Benefits Improvement and Protec-
15 tion Act of 2000, as enacted into law by section 1(a)(6) of
16 Public Law 106–554.

17 (2) SECRETARY.—The term “Secretary” means the
18 Secretary of Health and Human Services.

19 (d) TABLE OF CONTENTS.—The table of contents of this
20 Act is as follows:

Sec. 1. Short title; amendments to Social Security Act; references to BIPA
and Secretary; table of contents.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Sec. 101. Establishment of a medicare prescription drug benefit.

“PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

“Sec. 1860D–1. Benefits; eligibility; enrollment; and coverage period.

“Sec. 1860D–2. Requirements for qualified prescription drug coverage.

“Sec. 1860D–3. Beneficiary protections for qualified prescription drug
coverage.

“Sec. 1860D–4. Requirements for and contracts with prescription drug
plan (PDP) sponsors.

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- “Sec. 1860D–5. Process for beneficiaries to select qualified prescription drug coverage.
- “Sec. 1860D–6. Submission of bids and premiums.
- “Sec. 1860D–7. Premium and cost-sharing subsidies for low-income individuals.
- “Sec. 1860D–8. Subsidies for all medicare beneficiaries for qualified prescription drug coverage.
- “Sec. 1860D–9. Medicare Prescription Drug Trust Fund.
- “Sec. 1860D–10. Definitions; application to medicare advantage and EFFS programs; treatment of references to provisions in part C.
- Sec. 102. Offering of qualified prescription drug coverage under Medicare Advantage and enhanced fee-for-service (EFFS) program.
- Sec. 103. Medicaid amendments.
- “Sec. 1935. Special provisions relating to medicare prescription drug benefit.
- Sec. 104. Medigap transition.
- Sec. 105. Medicare prescription drug discount card endorsement program; transitional Rx assistance.
- Sec. 106. Disclosure of return information for purposes of carrying out medicare catastrophic prescription drug program.
- Sec. 107. State pharmaceutical assistance transition commission.

TITLE II—MEDICARE ENHANCED FEE-FOR-SERVICE AND
MEDICARE ADVANTAGE PROGRAMS; MEDICARE COMPETITION

- Sec. 200. Medicare modernization and revitalization.
- Subtitle A—Medicare Enhanced Fee-for-Service Program
- Sec. 201. Establishment of enhanced fee-for-service (EFFS) program under medicare.
- “PART E—ENHANCED FEE-FOR-SERVICE PROGRAM
- “Sec. 1860E–1. Offering of enhanced fee-for-service plans throughout the United States.
- “Sec. 1860E–2. Offering of enhanced fee-for-service (EFFS) plans.
- “Sec. 1860E–3. Submission of bids; beneficiary savings; payment of plans.
- “Sec. 1860E–4. Premiums; organizational and financial requirements; establishment of standards; contracts with EFFS organizations.

Subtitle B—Medicare Advantage Program

CHAPTER 1—IMPLEMENTATION OF PROGRAM

- Sec. 211. Implementation of medicare advantage program.
- Sec. 212. Medicare advantage improvements.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

- Sec. 221. Competition program beginning in 2006.

CHAPTER 3—ADDITIONAL REFORMS

- Sec. 231. Making permanent change in medicare advantage reporting deadlines and annual, coordinated election period.
- Sec. 232. Avoiding duplicative State regulation.
- Sec. 233. Specialized medicare advantage plans for special needs beneficiaries.
- Sec. 234. Medicare MSAs.
- Sec. 235. Extension of reasonable cost contracts.

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Subtitle C—Application of FEHBP-Style Competitive Reforms

- Sec. 241. Application of FEHBP-style competitive reform beginning in 2010.

TITLE III—COMBATting WASTE, FRAUD, AND ABUSE

- Sec. 301. Medicare secondary payor (MSP) provisions.
Sec. 302. Competitive acquisition of certain items and services.
Sec. 303. Competitive acquisition of covered outpatient drugs and biologicals.
Sec. 304. Demonstration project for use of recovery audit contractors.

TITLE IV—RURAL HEALTH CARE IMPROVEMENTS

- Sec. 401. Enhanced disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds.
Sec. 402. Immediate establishment of uniform standardized amount in rural and small urban areas.
Sec. 403. Establishment of essential rural hospital classification.
Sec. 404. More frequent update in weights used in hospital market basket.
Sec. 405. Improvements to critical access hospital program.
Sec. 406. Redistribution of unused resident positions.
Sec. 407. Two-year extension of hold harmless provisions for small rural hospitals and sole community hospitals under prospective payment system for hospital outpatient department services.
Sec. 408. Exclusion of certain rural health clinic and federally qualified health center services from the prospective payment system for skilled nursing facilities.
Sec. 409. Recognition of attending nurse practitioners as attending physicians to serve hospice patients.
Sec. 410. Improvement in payments to retain emergency capacity for ambulance services in rural areas.
Sec. 411. Providing safe harbor for certain collaborative efforts that benefit medically underserved populations.
Sec. 412. GAO study of geographic differences in payments for physicians' services.
Sec. 413. Treatment of missing cost reporting periods for sole community hospitals.
Sec. 414. Extension of telemedicine demonstration project.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

- Sec. 501. Revision of acute care hospital payment updates.
Sec. 502. Recognition of new medical technologies under inpatient hospital PPS.
Sec. 503. Increase in Federal rate for hospitals in Puerto Rico.
Sec. 504. Wage index adjustment reclassification reform .
Sec. 505. MedPAC report on specialty hospitals.

Subtitle B—Other Provisions

- Sec. 511. Payment for covered skilled nursing facility services.
Sec. 512. Coverage of hospice consultation services.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

- Sec. 601. Revision of updates for physicians' services.
Sec. 602. Studies on access to physicians' services.
Sec. 603. MedPAC report on payment for physicians' services.
Sec. 604. Inclusion of podiatrists under private contracting authority.

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SUBTITLE B—PREVENTIVE SERVICES

- Sec. 611. Coverage of an initial preventive physical examination.
- Sec. 612. Coverage of cholesterol and blood lipid screening.
- Sec. 613. Waiver of deductible for colorectal cancer screening tests.
- Sec. 614. Improved payment for certain mammography services.

Subtitle C—Other Services

- Sec. 621. Hospital outpatient department (HOPD) payment reform.
- Sec. 622. Payment for ambulance services.
- Sec. 623. Renal dialysis services.
- Sec. 624. One-year moratorium on therapy caps; provisions relating to reports.
- Sec. 625. Adjustment to payments for services furnished in ambulatory surgical centers.
- Sec. 626. Payment for certain shoes and inserts under the fee schedule for orthotics and prosthetics.
- Sec. 627. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
- Sec. 628. Part B deductible.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

- Sec. 701. Update in home health services.
- Sec. 702. Establishment of reduced copayment for a home health service episode of care for certain beneficiaries.
- Sec. 703. MedPAC study on medicare margins of home health agencies.

Subtitle B—Direct Graduate Medical Education

- Sec. 711. Extension of update limitation on high cost programs.

Subtitle C—Chronic Care Improvement

- Sec. 721. Voluntary chronic care improvement under traditional fee-for-service.
- Sec. 722. Chronic care improvement under medicare advantage and enhanced fee-for-service programs.
- Sec. 723. Institute of Medicine report.
- Sec. 724. MedPAC report.

Subtitle D—Other Provisions

- Sec. 731. Modifications to medicare payment advisory commission (MedPAC).
- Sec. 732. Demonstration project for medical adult day care services.
- Sec. 733. Improvements in national and local coverage determination process to respond to changes in technology.
- Sec. 734. Treatment of certain physician pathology services.

TITLE VIII—MEDICARE BENEFITS ADMINISTRATION

- Sec. 801. Establishment of Medicare Benefits Administration.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

- Sec. 901. Construction; definition of supplier.

“Supplier

- Sec. 902. Issuance of regulations.
- Sec. 903. Compliance with changes in regulations and policies.
- Sec. 904. Reports and studies relating to regulatory reform.

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Subtitle B—Contracting Reform

- Sec. 911. Increased flexibility in medicare administration.
- Sec. 912. Requirements for information security for medicare administrative contractors.

Subtitle C—Education and Outreach

- Sec. 921. Provider education and technical assistance.
- “Sec. 1889. Provider education and technical assistance.
- Sec. 922. Small provider technical assistance demonstration program.
- Sec. 923. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman.
- Sec. 924. Beneficiary outreach demonstration program.
- Sec. 925. Inclusion of additional information in notices to beneficiaries about skilled nursing facility benefits.
- Sec. 926. Information on medicare-certified skilled nursing facilities in hospital discharge plans.

Subtitle D—Appeals and Recovery

- Sec. 931. Transfer of responsibility for medicare appeals.
- Sec. 932. Process for expedited access to review.
- Sec. 933. Revisions to medicare appeals process.
- Sec. 934. Prepayment review.
- Sec. 935. Recovery of overpayments.
- Sec. 936. Provider enrollment process; right of appeal.
- Sec. 937. Process for correction of minor errors and omissions without pursuing appeals process.
- Sec. 938. Prior determination process for certain items and services; advance beneficiary notices.

Subtitle V—Miscellaneous Provisions

- Sec. 941. Policy development regarding evaluation and management (E & M) documentation guidelines.
- Sec. 942. Improvement in oversight of technology and coverage.
- Sec. 943. Treatment of hospitals for certain services under medicare secondary payor (MSP) provisions.
- Sec. 944. EMTALA improvements.
- Sec. 945. Emergency Medical Treatment and Active Labor Act (EMTALA) technical advisory group.
- Sec. 946. Authorizing use of arrangements to provide core hospice services in certain circumstances.
- Sec. 947. Application of osha bloodborne pathogens standard to certain hospitals.
- Sec. 948. BIPA-related technical amendments and corrections.
- Sec. 949. Conforming authority to waive a program exclusion.
- Sec. 950. Treatment of certain dental claims.
- Sec. 951. Furnishing hospitals with information to compute dsh formula.
- Sec. 952. Revisions to reassignment provisions.
- Sec. 953. Other provisions.
- Sec. 954. Temporary suspension of OASIS requirement for collection of data on non-medicare and non-medicaid patients.

**TITLE I—MEDICARE
PRESCRIPTION DRUG BENEFIT**

SEC. 101. ESTABLISHMENT OF A MEDICARE PRESCRIPTION DRUG BENEFIT.

(a) IN GENERAL.—Title XVIII is amended—

(1) by redesignating part D as part F; and

(2) by inserting after part C the following new part:

“PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT
PROGRAM

**“SEC. 1860D-1. BENEFITS; ELIGIBILITY; ENROLLMENT;
AND COVERAGE PERIOD.**

“(a) PROVISION OF QUALIFIED PRESCRIPTION DRUG
COVERAGE THROUGH ENROLLMENT IN PLANS.—Subject to
the succeeding provisions of this part, each individual who is
entitled to benefits under part A or is enrolled under part B
is entitled to obtain qualified prescription drug coverage (de-
scribed in section 1860D-2(a)) as follows:

“(1) MEDICARE-RELATED PLANS.—

“(A) MEDICARE ADVANTAGE.—If the individual is
eligible to enroll in a Medicare Advantage plan that
provides qualified prescription drug coverage under sec-
tion 1851(j), the individual may enroll in such plan and
obtain coverage through such plan.

“(B) EFFS PLANS.—If the individual is eligible to
enroll in an EFFS plan that provides qualified pre-
scription drug coverage under part E under section
1860E-2(d), the individual may enroll in such plan and
obtain coverage through such plan.

“(C) MA-EFFS PLAN; MA-EFFS RX PLAN.—For
purposes of this part, the term ‘MA-EFFS plan’ means
a Medicare Advantage plan under part C and an EFFS
plan under part E and the term ‘MA-EFFS Rx plan’
means a MA-EFFS plan insofar as such plan provides
qualified prescription drug coverage.

“(2) PRESCRIPTION DRUG PLAN.—If the individual is
not enrolled in a MA-EFFS plan , the individual may en-

1 roll under this part in a prescription drug plan (as defined
2 in section 1860D-10(a)(5)).

3 Such individuals shall have a choice of such plans under section
4 1860D-5(d).

5 “(b) GENERAL ELECTION PROCEDURES.—

6 “(1) IN GENERAL.—An individual eligible to make an
7 election under subsection (a) may elect to enroll in a pre-
8 scription drug plan under this part, or elect the option of
9 qualified prescription drug coverage under a MA-EFFS Rx
10 plan under part C or part E, and to change such election
11 only in such manner and form as may be prescribed by reg-
12 ulations of the Administrator of the Medicare Benefits Ad-
13 ministration (appointed under section 1809(b)) (in this
14 part referred to as the ‘Medicare Benefits Administrator’)
15 and only during an election period prescribed in or under
16 this subsection.

17 “(2) ELECTION PERIODS.—

18 “(A) IN GENERAL.—Except as provided in this
19 paragraph, the election periods under this subsection
20 shall be the same as the coverage election periods
21 under the Medicare Advantage and EFFS programs
22 under section 1851(e), including—

23 “(i) annual coordinated election periods; and

24 “(ii) special election periods.

25 In applying the last sentence of section 1851(e)(4) (re-
26 lating to discontinuance of an election during the first
27 year of eligibility) under this subparagraph, in the case
28 of an election described in such section in which the in-
29 dividual had elected or is provided qualified prescrip-
30 tion drug coverage at the time of such first enrollment,
31 the individual shall be permitted to enroll in a prescrip-
32 tion drug plan under this part at the time of the elec-
33 tion of coverage under the original fee-for-service plan.

34 “(B) INITIAL ELECTION PERIODS.—

35 “(i) INDIVIDUALS CURRENTLY COVERED.—In
36 the case of an individual who is entitled to benefits
37 under part A or enrolled under part B as of Octo-

ber 1, 2005, there shall be an initial election period of 6 months beginning on that date.

“(ii) INDIVIDUAL COVERED IN FUTURE.—In the case of an individual who is first entitled to benefits under part A or enrolled under part B after such date, there shall be an initial election period which is the same as the initial enrollment period under section 1837(d).

“(C) ADDITIONAL SPECIAL ELECTION PERIODS.—The Administrator shall establish special election periods—

“(i) in cases of individuals who have and involuntarily lose prescription drug coverage described in subsection (c)(2)(C);

“(ii) in cases described in section 1837(h) (relating to errors in enrollment), in the same manner as such section applies to part B;

“(iii) in the case of an individual who meets such exceptional conditions (including conditions provided under section 1851(e)(4)(D)) as the Administrator may provide; and

“(iv) in cases of individuals (as determined by the Administrator) who become eligible for prescription drug assistance under title XIX under section 1935(d).

“(3) INFORMATION ON PLANS.—Information described in section 1860D-3(b)(1) on prescription drug plans shall be made available during election periods.

“(c) GUARANTEED ISSUE; COMMUNITY RATING; AND NONDISCRIMINATION.—

“(1) GUARANTEED ISSUE.—

“(A) IN GENERAL.—An eligible individual who is eligible to elect qualified prescription drug coverage under a prescription drug plan or MA-EFFS Rx plan at a time during which elections are accepted under this part with respect to the plan shall not be denied enrollment based on any health status-related factor

(described in section 2702(a)(1) of the Public Health Service Act) or any other factor.

“(B) MEDICARE ADVANTAGE LIMITATIONS PERMITTED.—The provisions of paragraphs (2) and (3) (other than subparagraph (C)(i), relating to default enrollment) of section 1851(g) (relating to priority and limitation on termination of election) shall apply to PDP sponsors under this subsection.

“(2) COMMUNITY-RATED PREMIUM.—

“(A) IN GENERAL.—In the case of an individual who enrolls under a prescription drug plan or in a MA-EFFS Rx plan during the individual’s initial enrollment period under this part or maintains (as determined under subparagraph (C)) continuous prescription drug coverage since the date the individual first qualifies to elect prescription drug coverage under this part, a PDP sponsor or entity offering a prescription drug plan or MA-EFFS Rx plan and in which the individual is enrolled may not deny, limit, or condition the coverage or provision of covered prescription drug benefits or vary or increase the premium under the plan based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act or any other factor.

“(B) LATE ENROLLMENT PENALTY.—In the case of an individual who does not maintain such continuous prescription drug coverage (as described in subparagraph (C)), a PDP sponsor or an entity offering a MA-EFFS Rx plan may (notwithstanding any provision in this title) adjust the premium otherwise applicable or impose a pre-existing condition exclusion with respect to qualified prescription drug coverage in a manner that reflects additional actuarial risk involved. Such a risk shall be established through an appropriate actuarial opinion of the type described in subparagraphs (A) through (C) of section 2103(c)(4).

1 “(C) CONTINUOUS PRESCRIPTION DRUG COV-
2 ERAGE.—An individual is considered for purposes of
3 this part to be maintaining continuous prescription
4 drug coverage on and after the date the individual first
5 qualifies to elect prescription drug coverage under this
6 part if the individual establishes that as of such date
7 the individual is covered under any of the following pre-
8 scription drug coverage and before the date that is the
9 last day of the 63-day period that begins on the date
10 of termination of the particular prescription drug cov-
11 erage involved (regardless of whether the individual
12 subsequently obtains any of the following prescription
13 drug coverage):

14 “(i) COVERAGE UNDER PRESCRIPTION DRUG
15 PLAN OR MA-EFFS RX PLAN.—Qualified prescrip-
16 tion drug coverage under a prescription drug plan
17 or under a MA-EFFS Rx plan.

18 “(ii) MEDICAID PRESCRIPTION DRUG COV-
19 ERAGE.—Prescription drug coverage under a med-
20 icaid plan under title XIX, including through the
21 Program of All-inclusive Care for the Elderly
22 (PACE) under section 1934, through a social
23 health maintenance organization (referred to in
24 section 4104(c) of the Balanced Budget Act of
25 1997), or through a demonstration project under
26 part C that demonstrates the application of capita-
27 tion payment rates for frail elderly medicare bene-
28 ficiaries through the use of an interdisciplinary
29 team and through the provision of primary care
30 services to such beneficiaries by means of such a
31 team at the nursing facility involved.

32 “(iii) PRESCRIPTION DRUG COVERAGE UNDER
33 GROUP HEALTH PLAN.—Any outpatient prescrip-
34 tion drug coverage under a group health plan, in-
35 cluding a health benefits plan under the Federal
36 Employees Health Benefit Plan under chapter 89
37 of title 5, United States Code, and a qualified re-

1 three prescription drug plan as defined in section
2 1860D-8(f)(1), but only if (subject to subpara-
3 graph (E)(ii)) the coverage provides benefits at
4 least equivalent to the benefits under a qualified
5 prescription drug plan.

6 “(iv) PRESCRIPTION DRUG COVERAGE UNDER
7 CERTAIN MEDIGAP POLICIES.—Coverage under a
8 medicare supplemental policy under section 1882
9 that provides benefits for prescription drugs
10 (whether or not such coverage conforms to the
11 standards for packages of benefits under section
12 1882(p)(1)), but only if the policy was in effect on
13 January 1, 2006, and if (subject to subparagraph
14 (E)(ii)) the coverage provides benefits at least
15 equivalent to the benefits under a qualified pre-
16 scription drug plan.

17 “(v) STATE PHARMACEUTICAL ASSISTANCE
18 PROGRAM.—Coverage of prescription drugs under a
19 State pharmaceutical assistance program, but only
20 if (subject to subparagraph (E)(ii)) the coverage
21 provides benefits at least equivalent to the benefits
22 under a qualified prescription drug plan.

23 “(vi) VETERANS’ COVERAGE OF PRESCRIPTION
24 DRUGS.—Coverage of prescription drugs for vet-
25 erans under chapter 17 of title 38, United States
26 Code, but only if (subject to subparagraph (E)(ii))
27 the coverage provides benefits at least equivalent to
28 the benefits under a qualified prescription drug
29 plan.

30 “(D) CERTIFICATION.—For purposes of carrying
31 out this paragraph, the certifications of the type de-
32 scribed in sections 2701(e) of the Public Health Service
33 Act and in section 9801(e) of the Internal Revenue
34 Code shall also include a statement for the period of
35 coverage of whether the individual involved had pre-
36 scription drug coverage described in subparagraph (C).

37 “(E) DISCLOSURE.—

12

1 “(i) IN GENERAL.—Each entity that offers
2 coverage of the type described in clause (iii), (iv),
3 (v), or (vi) of subparagraph (C) shall provide for
4 disclosure, consistent with standards established by
5 the Administrator, of whether such coverage pro-
6 vides benefits at least equivalent to the benefits
7 under a qualified prescription drug plan.

8 “(ii) WAIVER OF LIMITATIONS.—An individual
9 may apply to the Administrator to waive the re-
10 quirement that coverage of such type provide bene-
11 fits at least equivalent to the benefits under a
12 qualified prescription drug plan, if the individual
13 establishes that the individual was not adequately
14 informed that such coverage did not provide such
15 level of benefits.

16 “(F) CONSTRUCTION.—Nothing in this section
17 shall be construed as preventing the disenrollment of
18 an individual from a prescription drug plan or a MA-
19 EFFS Rx plan based on the termination of an election
20 described in section 1851(g)(3), including for non-pay-
21 ment of premiums or for other reasons specified in sub-
22 section (d)(3), which takes into account a grace period
23 described in section 1851(g)(3)(B)(i).

24 “(3) NONDISCRIMINATION.—A PDP sponsor that of-
25 fers a prescription drug plan in an area designated under
26 section 1860D-4(b)(5) shall make such plan available to all
27 eligible individuals residing in the area without regard to
28 their health or economic status or their place of residence
29 within the area.

30 “(d) EFFECTIVE DATE OF ELECTIONS.—

31 “(1) IN GENERAL.—Except as provided in this section,
32 the Administrator shall provide that elections under sub-
33 section (b) take effect at the same time as the Adminis-
34 trator provides that similar elections under section 1851(e)
35 take effect under section 1851(f).

36 “(2) NO ELECTION EFFECTIVE BEFORE 2006.—In no
37 case shall any election take effect before January 1, 2006.

1 “(3) TERMINATION.—The Administrator shall provide
2 for the termination of an election in the case of—

3 “(A) termination of coverage under both part A
4 and part B; and

5 “(B) termination of elections described in section
6 1851(g)(3) (including failure to pay required pre-
7 miums).

8 **“SEC. 1860D-2. REQUIREMENTS FOR QUALIFIED PRE-**
9 **SCRIPTION DRUG COVERAGE.**

10 “(a) REQUIREMENTS.—

11 “(1) IN GENERAL.—For purposes of this part and
12 part C and part E, the term ‘qualified prescription drug
13 coverage’ means either of the following:

14 “(A) STANDARD COVERAGE WITH ACCESS TO NE-
15 GOTIATED PRICES.—Standard coverage (as defined in
16 subsection (b)) and access to negotiated prices under
17 subsection (d).

18 “(B) ACTUARIALLY EQUIVALENT COVERAGE WITH
19 ACCESS TO NEGOTIATED PRICES.—Coverage of covered
20 outpatient drugs which meets the alternative coverage
21 requirements of subsection (c) and access to negotiated
22 prices under subsection (d), but only if it is approved
23 by the Administrator, as provided under subsection (c).

24 “(2) PERMITTING ADDITIONAL OUTPATIENT PRE-
25 SCRIPTON DRUG COVERAGE.—

26 “(A) IN GENERAL.—Subject to subparagraph (B),
27 nothing in this part shall be construed as preventing
28 qualified prescription drug coverage from including cov-
29 erage of covered outpatient drugs that exceeds the cov-
30 erage required under paragraph (1), but any such addi-
31 tional coverage shall be limited to coverage of covered
32 outpatient drugs.

33 “(B) DISAPPROVAL AUTHORITY.—The Adminis-
34 trator shall review the offering of qualified prescription
35 drug coverage under this part or part C or E. If the
36 Administrator finds that, in the case of a qualified pre-
37 scription drug coverage under a prescription drug plan

1 or a MA-EFFS Rx plan, that the organization or spon-
2 sor offering the coverage is engaged in activities in-
3 tended to discourage enrollment of classes of eligible
4 medicare beneficiaries obtaining coverage through the
5 plan on the basis of their higher likelihood of utilizing
6 prescription drug coverage, the Administrator may ter-
7minate the contract with the sponsor or organization
8 under this part or part C or E.

9 “(3) APPLICATION OF SECONDARY PAYOR PROVI-
10 SIONS.—The provisions of section 1852(a)(4) shall apply
11 under this part in the same manner as they apply under
12 part C.

13 “(b) STANDARD COVERAGE.—For purposes of this part,
14 the ‘standard coverage’ is coverage of covered outpatient drugs
15 (as defined in subsection (f)) that meets the following require-
16 ments:

17 “(1) DEDUCTIBLE.—The coverage has an annual
18 deductible—

19 “(A) for 2006, that is equal to \$250; or

20 “(B) for a subsequent year, that is equal to the
21 amount specified under this paragraph for the previous
22 year increased by the percentage specified in paragraph
23 (5) for the year involved.

24 Any amount determined under subparagraph (B) that is
25 not a multiple of \$10 shall be rounded to the nearest mul-
26 tiple of \$10.

27 “(2) 80:20 BENEFIT STRUCTURE.—

28 “(A) 20 PERCENT COINSURANCE.—The coverage
29 has cost-sharing (for costs above the annual deductible
30 specified in paragraph (1) and up to the initial cov-
31 erage limit under paragraph (3)) that is—

32 “(i) equal to 20 percent; or

33 “(ii) is actuarially equivalent (using processes
34 established under subsection (e)) to an average ex-
35 pected payment of 20 percent of such costs.

36 “(B) USE OF TIERS.—Nothing in this part shall
37 be construed as preventing a PDP sponsor from apply-

1 ing tiered copayments, so long as such tiered copay-
2 ments are consistent with subparagraph (A).

3 “(3) INITIAL COVERAGE LIMIT.—Subject to paragraph
4 (4), the coverage has an initial coverage limit on the max-
5 imum costs that may be recognized for payment
6 purposes—

7 “(A) for 2006, that is equal to \$2,000; or

8 “(B) for a subsequent year, that is equal to the
9 amount specified in this paragraph for the previous
10 year, increased by the annual percentage increase de-
11 scribed in paragraph (5) for the year involved.

12 Any amount determined under subparagraph (B) that is
13 not a multiple of \$25 shall be rounded to the nearest mul-
14 tiple of \$25.

15 “(4) CATASTROPHIC PROTECTION.—

16 “(A) IN GENERAL.—Notwithstanding paragraph
17 (3), the coverage provides benefits with no cost-sharing
18 after the individual has incurred costs (as described in
19 subparagraph (C)) for covered outpatient drugs in a
20 year equal to the annual out-of-pocket threshold speci-
21 fied in subparagraph (B).

22 “(B) ANNUAL OUT-OF-POCKET THRESHOLD.—

23 “(i) IN GENERAL.—For purposes of this part,
24 the ‘annual out-of-pocket threshold’ specified in
25 this subparagraph is equal to \$3,500 (subject to
26 adjustment under clause (ii) and subparagraph
27 (D)).

28 “(ii) INFLATION INCREASE.—For a year after
29 2006, the dollar amount specified in clause (i) shall
30 be increased by the annual percentage increase de-
31 scribed in paragraph (5) for the year involved. Any
32 amount determined under the previous sentence
33 that is not a multiple of \$100 shall be rounded to
34 the nearest multiple of \$100.

35 “(C) APPLICATION.—In applying subparagraph
36 (A)—

1 “(i) incurred costs shall only include costs in-
2 curred for the annual deductible (described in para-
3 graph (1)), cost-sharing (described in paragraph
4 (2)), and amounts for which benefits are not pro-
5 vided because of the application of the initial cov-
6 erage limit described in paragraph (3); and

7 “(ii) such costs shall be treated as incurred
8 only if they are paid by the individual (or by an-
9 other individual, such as a family member, on be-
10 half of the individual), under section 1860D-7,
11 under title XIX and the individual (or other indi-
12 vidual) is not reimbursed through insurance or oth-
13 erwise, a group health plan, or other third-party
14 payment arrangement (other than under such title)
15 for such costs.

16 “(D) ADJUSTMENT OF ANNUAL OUT-OF-POCKET
17 THRESHOLDS.—

18 “(i) IN GENERAL.—For each enrollee in a pre-
19 scription drug plan or in a MA-EFFS Rx plan
20 whose adjusted gross income exceeds the income
21 threshold as defined in clause (ii) for a year, the
22 annual out-of-pocket threshold otherwise deter-
23 mined under subparagraph (B) for such year shall
24 be increased by an amount equal to the percentage
25 specified in clause (iii), multiplied by the lesser
26 of—

27 “(I) the amount of such excess; or

28 “(II) the amount by which the income
29 threshold limit exceeds the income threshold.

30 Any amount determined under the previous sen-
31 tence that is not a multiple of \$100 shall be round-
32 ed to the nearest multiple of \$100.

33 “(ii) INCOME THRESHOLD.—For purposes of
34 clause (i)—

35 “(I) IN GENERAL.—Subject to subclause
36 (II), the term ‘income threshold’ means

1 \$60,000 and the term ‘income threshold limit’
2 means \$200,000.

3 “(II) INCOME INFLATION ADJUSTMENT.—
4 In the case of a year beginning after 2006,
5 each of the dollar amounts in subclause (I)
6 shall be increased by an amount equal to such
7 dollar amount multiplied by the cost-of-living
8 adjustment determined under section 1(f)(3) of
9 the Internal Revenue Code of 1986 for such
10 year, determined by substituting ‘calendar year
11 2005’ for ‘calendar year 1992’. If any amount
12 increased under the previous sentence is not a
13 multiple of \$100, such amount shall be round-
14 ed to the nearest multiple of \$100.

15 “(iii) PERCENTAGE.—The percentage specified
16 in this clause for a year is a fraction (expressed as
17 a percentage) equal to—

18 “(I) the annual-of-out pocket threshold for
19 a year under subparagraph (B) (determined
20 without regard to this subparagraph), divided
21 by

22 “(II) the income threshold under clause
23 (ii) for that year.

24 If any percentage determined under the previous
25 sentence that is not a multiple of $\frac{1}{10}$ th of 1 per-
26 centage point, such percentage shall be rounded to
27 the nearest multiple of $\frac{1}{10}$ th of 1 percentage point.

28 “(iv) USE OF MOST RECENT RETURN INFOR-
29 MATION.—For purposes of clause (i) for an enrollee
30 for a year, except as provided in clause (v), the ad-
31 justed gross income of an individual shall be based
32 on the most recent information disclosed to the
33 Secretary under section 6109(l)(19) of the Internal
34 Revenue Code of 1986 before the beginning of that
35 year.

36 “(v) INDIVIDUAL ELECTION TO PRESENT MOST
37 RECENT INFORMATION REGARDING INCOME.—The

18

1 Secretary shall provide, in coordination with the
2 Secretary of the Treasury, a procedure under
3 which, for purposes of applying this subparagraph
4 for a calendar year, instead of using the informa-
5 tion described in clause (iv), an enrollee may elect
6 to use more recent information, including informa-
7 tion with respect to a taxable year ending in such
8 calendar year. Such process shall—

9 “(I) require the enrollee to provide the
10 Secretary with a copy of the relevant portion of
11 the more recent return to be used under this
12 clause;

13 “(II) provide for the Medicare Beneficiary
14 Ombudsman (under section 1810) offering as-
15 sistance to such enrollees in presenting such in-
16 formation and the toll-free number under such
17 section being a point of contact for bene-
18 ficiaries to inquire as to how to present such
19 information;

20 “(III) provide for the verification of the
21 information in such return by the Secretary of
22 the Treasury under section 6103(l)(19) of the
23 Internal Revenue Code of 1986; and

24 “(IV) provide for the payment by the Sec-
25 retary (in a manner specified by the Secretary)
26 to the enrollee of an amount equal to the excess
27 of the benefit payments that would have been
28 payable under the plan if the more recent re-
29 turn information were used, over the benefit
30 payments that were made under the plan.

31 In the case of a payment under subclause (III) for
32 an enrollee under a prescription drug plan, the
33 PDP sponsor of the plan shall pay to the Secretary
34 the amount so paid, less the applicable reinsurance
35 amount that would have applied under section
36 1860D-8(c)(1)(B) if such payment had been treat-
37 ed as an allowable cost under such section. Such

1 plan payment shall be deposited in the Treasury to
2 the credit of the Medicare Prescription Drug Ac-
3 count in the Federal Supplementary Medical Insur-
4 ance Trust Fund (under section 1841).

5 “(vi) DISSEMINATION OF INFORMATION ON
6 PROCESS.—The Secretary shall provide, through
7 the annual medicare handbook under section
8 1804(a), for a general description of the adjust-
9 ment of annual out-of-pocket thresholds provided
10 under this subparagraph, including the process for
11 adjustment based upon more recent information
12 and the confidentiality provisions of subparagraph
13 (F), and shall provide for dissemination of a table
14 for each year that sets forth the amount of the ad-
15 justment that is made under clause (i) based on the
16 amount of an enrollee’s adjusted gross income.

17 “(E) REQUESTING INFORMATION ON ENROLL-
18 EES.—

19 “(i) IN GENERAL.—The Secretary shall, peri-
20 odically as required to carry out subparagraph (D),
21 transmit to the Secretary of the Treasury a list of
22 the names and TINs of enrollees in prescription
23 drug plans (or in MA-EFFS Rx plans) and request
24 that such Secretary disclose to the Secretary infor-
25 mation under subparagraph (A) of section
26 6103(l)(19) of the Internal Revenue Code of 1986
27 with respect to those enrollees for a specified tax-
28 able year for application in a particular calendar
29 year.

30 “(ii) DISCLOSURE TO PLAN SPONSORS.—In
31 the case of a specified taxpayer (as defined in sec-
32 tion 6103(l)(19)(B) of the Internal Revenue Code
33 of 1986) who is enrolled in a prescription drug plan
34 or in an MA-EFFS Rx plan, the Secretary shall
35 disclose to the entity that offers the plan the an-
36 nual out-of-pocket threshold applicable to such in-
37 dividual under subparagraph (D).

20

1 “(F) MAINTAINING CONFIDENTIALITY OF INFOR-
2 MATION.—

3 “(i) IN GENERAL.—The amount of any in-
4 crease in an annual out-of-pocket threshold under
5 subparagraph (D) may not be disclosed by the Sec-
6 retary except to a PDP sponsor or entity that of-
7 fers a MA-EFFS Rx plan to the extent necessary
8 to carry out this part.

9 “(ii) CRIMINAL AND CIVIL PENALTIES FOR UN-
10 AUTHORIZED DISCLOSURE.—A person who makes
11 an unauthorized disclosure of information disclosed
12 under section 6103(l)(19) of the Internal Revenue
13 Code of 1986 (including disclosure of any increase
14 in an annual out-of-pocket threshold under sub-
15 paragraph (D)) shall be subject to penalty to the
16 extent provided under—

17 “(I) section 7213 of such Code (relating to
18 criminal penalty for unauthorized disclosure of
19 information);

20 “(II) section 7213A of such Code (relating
21 to criminal penalty for unauthorized inspection
22 of returns or return information);

23 “(III) section 7431 of such Code (relating
24 to civil damages for unauthorized inspection or
25 disclosure of returns and return information);

26 “(IV) any other provision of the Internal
27 Revenue Code of 1986; or

28 “(V) any other provision of law.

29 “(iii) APPLICATION OF ADDITIONAL CIVIL
30 MONETARY PENALTY FOR UNAUTHORIZED DISCLO-
31 SURES.—In addition to any penalty otherwise pro-
32 vided under law, any person who makes an unau-
33 thorized disclosure of such information shall be
34 subject to a civil monetary penalty of not to exceed
35 \$10,000 for each such unauthorized disclosure. The
36 provisions of section 1128A (other than subsections
37 (a) and (b)) shall apply to civil money penalties

1 under this subparagraph in the same manner as
2 they apply to a penalty or proceeding under section
3 1128A(a).

4 “(5) ANNUAL PERCENTAGE INCREASE.—For purposes
5 of this part, the annual percentage increase specified in
6 this paragraph for a year is equal to the annual percentage
7 increase in average per capita aggregate expenditures for
8 covered outpatient drugs in the United States for medicare
9 beneficiaries, as determined by the Administrator for the
10 12-month period ending in July of the previous year.

11 “(c) ALTERNATIVE COVERAGE REQUIREMENTS.—A pre-
12 scription drug plan or MA-EFFS Rx plan may provide a dif-
13 ferent prescription drug benefit design from the standard cov-
14 erage described in subsection (b) so long as the Administrator
15 determines (based on an actuarial analysis by the Adminis-
16 trator) that the following requirements are met and the plan
17 applies for, and receives, the approval of the Administrator for
18 such benefit design:

19 “(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT
20 COVERAGE.—

21 “(A) ASSURING EQUIVALENT VALUE OF TOTAL
22 COVERAGE.—The actuarial value of the total coverage
23 (as determined under subsection (e)) is at least equal
24 to the actuarial value (as so determined) of standard
25 coverage.

26 “(B) ASSURING EQUIVALENT UNSUBSIDIZED
27 VALUE OF COVERAGE.—The unsubsidized value of the
28 coverage is at least equal to the unsubsidized value of
29 standard coverage. For purposes of this subparagraph,
30 the unsubsidized value of coverage is the amount by
31 which the actuarial value of the coverage (as deter-
32 mined under subsection (e)) exceeds the actuarial value
33 of the subsidy payments under section 1860D–8 with
34 respect to such coverage.

35 “(C) ASSURING STANDARD PAYMENT FOR COSTS
36 AT INITIAL COVERAGE LIMIT.—The coverage is de-
37 signed, based upon an actuarially representative pat-

1 tern of utilization (as determined under subsection (e)),
2 to provide for the payment, with respect to costs in-
3 curred that are equal to the initial coverage limit under
4 subsection (b)(3), of an amount equal to at least the
5 product of—

6 “(i) the amount by which the initial coverage
7 limit described in subsection (b)(3) exceeds the de-
8 ductible described in subsection (b)(1); and

9 “(ii) 100 percent minus the cost-sharing per-
10 centage specified in subsection (b)(2)(A)(i).

11 “(2) CATASTROPHIC PROTECTION.—The coverage pro-
12 vides for beneficiaries the catastrophic protection described
13 in subsection (b)(4).

14 “(d) ACCESS TO NEGOTIATED PRICES.—

15 “(1) IN GENERAL.—Under qualified prescription drug
16 coverage offered by a PDP sponsor or an entity offering a
17 MA-EFFS Rx plan, the sponsor or entity shall provide
18 beneficiaries with access to negotiated prices (including ap-
19 plicable discounts) used for payment for covered outpatient
20 drugs, regardless of the fact that no benefits may be pay-
21 able under the coverage with respect to such drugs because
22 of the application of cost-sharing or an initial coverage
23 limit (described in subsection (b)(3)). Insofar as a State
24 elects to provide medical assistance under title XIX for a
25 drug based on the prices negotiated by a prescription drug
26 plan or MA-EFFS Rx plan under this part, the require-
27 ments of section 1927 shall not apply to such drugs. The
28 prices negotiated by a prescription drug plan under this
29 part, by a MA-EFFS Rx plan with respect to covered out-
30 patient drugs, or by a qualified retiree prescription drug
31 plan (as defined in section 1860D-8(f)(1)) with respect to
32 such drugs on behalf of individuals entitled to benefits
33 under part A or enrolled under part B, shall (notwith-
34 standing any other provision of law) not be taken into ac-
35 count for the purposes of establishing the best price under
36 section 1927(c)(1)(C).

23

1 “(2) DISCLOSURE.—The PDP sponsor or entity offer-
2 ing a MA-EFFS Rx plan shall disclose to the Adminis-
3 trator (in a manner specified by the Administrator) the ex-
4 tent to which discounts or rebates or other remuneration
5 or price concessions made available to the sponsor or orga-
6 nization by a manufacturer are passed through to enrollees
7 through pharmacies and other dispensers or otherwise. The
8 provisions of section 1927(b)(3)(D) shall apply to informa-
9 tion disclosed to the Administrator under this paragraph in
10 the same manner as such provisions apply to information
11 disclosed under such section.

12 “(3) AUDITS AND REPORTS.—To protect against fraud
13 and abuse and to ensure proper disclosures and accounting
14 under this part, in addition to any protections against
15 fraud and abuse provided under section 1860D–4(b)(3)(C),
16 the Administrator may periodically audit the financial
17 statements and records of PDP sponsor or entities offering
18 a MA-EFFS Rx plan.

19 “(e) ACTUARIAL VALUATION; DETERMINATION OF AN-
20 NUAL PERCENTAGE INCREASES.—

21 “(1) PROCESSES.—For purposes of this section, the
22 Administrator shall establish processes and methods—

23 “(A) for determining the actuarial valuation of
24 prescription drug coverage, including—

25 “(i) an actuarial valuation of standard cov-
26 erage and of the reinsurance subsidy payments
27 under section 1860D–8;

28 “(ii) the use of generally accepted actuarial
29 principles and methodologies; and

30 “(iii) applying the same methodology for de-
31 terminations of alternative coverage under sub-
32 section (c) as is used with respect to determina-
33 tions of standard coverage under subsection (b);
34 and

35 “(B) for determining annual percentage increases
36 described in subsection (b)(5).

24

1 “(2) USE OF OUTSIDE ACTUARIES.—Under the proc-
2 esses under paragraph (1)(A), PDP sponsors and entities
3 offering MA-EFFS Rx plans may use actuarial opinions
4 certified by independent, qualified actuaries to establish ac-
5 tuarial values, but the Administrator shall determine
6 whether such actuarial values meet the requirements under
7 subsection (c)(1).

8 “(f) COVERED OUTPATIENT DRUGS DEFINED.—

9 “(1) IN GENERAL.—Except as provided in this sub-
10 section, for purposes of this part, the term ‘covered out-
11 patient drug’ means—

12 “(A) a drug that may be dispensed only upon a
13 prescription and that is described in subparagraph
14 (A)(i) or (A)(ii) of section 1927(k)(2); or

15 “(B) a biological product described in clauses (i)
16 through (iii) of subparagraph (B) of such section or in-
17 sulin described in subparagraph (C) of such section and
18 medical supplies associated with the injection of insulin
19 (as defined in regulations of the Secretary),
20 and such term includes a vaccine licensed under section
21 351 of the Public Health Service Act and any use of a cov-
22 ered outpatient drug for a medically accepted indication (as
23 defined in section 1927(k)(6)).

24 “(2) EXCLUSIONS.—

25 “(A) IN GENERAL.—Such term does not include
26 drugs or classes of drugs, or their medical uses, which
27 may be excluded from coverage or otherwise restricted
28 under section 1927(d)(2), other than subparagraph (E)
29 thereof (relating to smoking cessation agents), or under
30 section 1927(d)(3).

31 “(B) AVOIDANCE OF DUPLICATE COVERAGE.—A
32 drug prescribed for an individual that would otherwise
33 be a covered outpatient drug under this part shall not
34 be so considered if payment for such drug is available
35 under part A or B for an individual entitled to benefits
36 under part A and enrolled under part B.

1 “(3) APPLICATION OF FORMULARY RESTRICTIONS.—A
2 drug prescribed for an individual that would otherwise be
3 a covered outpatient drug under this part shall not be so
4 considered under a plan if the plan excludes the drug under
5 a formulary and such exclusion is not successfully appealed
6 under section 1860D–3(f)(2).

7 “(4) APPLICATION OF GENERAL EXCLUSION PROVI-
8 SIONS.—A prescription drug plan or MA-EFFS Rx plan
9 may exclude from qualified prescription drug coverage any
10 covered outpatient drug—

11 “(A) for which payment would not be made if sec-
12 tion 1862(a) applied to part D; or

13 “(B) which are not prescribed in accordance with
14 the plan or this part.

15 Such exclusions are determinations subject to reconsider-
16 ation and appeal pursuant to section 1860D–3(f).

17 **“SEC. 1860D–3. BENEFICIARY PROTECTIONS FOR QUALI-**
18 **FIED PRESCRIPTION DRUG COVERAGE.**

19 “(a) GUARANTEED ISSUE, COMMUNITY-RATED PREMIUMS,
20 ACCESS TO NEGOTIATED PRICES, AND NONDISCRIMINATION.—
21 For provisions requiring guaranteed issue, community-rated
22 premiums, access to negotiated prices, and nondiscrimination,
23 see sections 1860D–1(c)(1), 1860D–1(c)(2), 1860D–2(d), and
24 1860D–6(b), respectively.

25 “(b) DISSEMINATION OF INFORMATION.—

26 “(1) GENERAL INFORMATION.—A PDP sponsor shall
27 disclose, in a clear, accurate, and standardized form to
28 each enrollee with a prescription drug plan offered by the
29 sponsor under this part at the time of enrollment and at
30 least annually thereafter, the information described in sec-
31 tion 1852(c)(1) relating to such plan. Such information in-
32 cludes the following:

33 “(A) Access to specific covered outpatient drugs,
34 including access through pharmacy networks.

35 “(B) How any formulary used by the sponsor
36 functions, including the drugs included in the for-
37 mulary.

1 “(C) Co-payments and deductible requirements,
2 including the identification of the tiered or other co-
3 payment level applicable to each drug (or class of
4 drugs).

5 “(D) Grievance and appeals procedures.

6 Such information shall also be made available upon request
7 to prospective enrollees.

8 “(2) DISCLOSURE UPON REQUEST OF GENERAL COV-
9 ERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—
10 Upon request of an individual eligible to enroll under a pre-
11 scription drug plan, the PDP sponsor shall provide the in-
12 formation described in section 1852(c)(2) (other than sub-
13 paragraph (D)) to such individual.

14 “(3) RESPONSE TO BENEFICIARY QUESTIONS.—Each
15 PDP sponsor offering a prescription drug plan shall have
16 a mechanism for providing specific information to enrollees
17 upon request. The sponsor shall make available on a timely
18 basis, through an Internet website and in writing upon re-
19 quest, information on specific changes in its formulary.

20 “(4) CLAIMS INFORMATION.—Each PDP sponsor of-
21 fering a prescription drug plan must furnish to each en-
22 rollee in a form easily understandable to such enrollees an
23 explanation of benefits (in accordance with section 1806(a)
24 or in a comparable manner) and a notice of the benefits
25 in relation to initial coverage limit and the annual out-of-
26 pocket threshold applicable to such enrollee for the current
27 year, whenever prescription drug benefits are provided
28 under this part (except that such notice need not be pro-
29 vided more often than monthly).

30 “(c) ACCESS TO COVERED BENEFITS.—

31 “(1) ASSURING PHARMACY ACCESS.—

32 “(A) SECURING SUFFICIENT PARTICIPATION.—

33 “(i) PARTICIPATION OF ANY WILLING PHAR-
34 MACY.—A PDP sponsor and an entity offering a
35 MA-EFFS Rx plan shall permit the participation
36 of any pharmacy that meets terms and conditions
37 that the plan has established.

1 “(ii) DISCOUNTS ALLOWED FOR NETWORK
2 PHARMACIES.—A prescription drug plan and a MA-
3 EFFS Rx plan may, notwithstanding clause (i), re-
4 duce copayments for its enrolled beneficiaries below
5 the level otherwise provided for covered outpatient
6 drugs dispensed through in-network pharmacies,
7 but in no case shall such a reduction result in an
8 increase in payments made by the Administrator
9 under section 1860D–8 to a plan.

10 “(iii) CONVENIENT ACCESS FOR NETWORK
11 PHARMACIES.—The PDP sponsor of the prescrip-
12 tion drug plan and the entity offering a MA-EFFS
13 Rx plan shall secure the participation in its net-
14 work of a sufficient number of pharmacies that dis-
15 pense (other than by mail order) drugs directly to
16 patients to ensure convenient access (consistent
17 with rules of the Administrator established under
18 subparagraph (B)). The Administrator shall estab-
19 lish convenient access rules under this clause that
20 are no less favorable to enrollees than the rules for
21 convenient access to pharmacies of the Secretary of
22 Defense established as of June 1, 2003, for pur-
23 poses of the TRICARE Retail Pharmacy (TRRx)
24 program. Such rules shall include adequate emer-
25 gency access for enrolled beneficiaries.

26 “(iv) LEVEL PLAYING FIELD.—Such a sponsor
27 shall permit enrollees to receive benefits (which
28 may include a 90-day supply of drugs or
29 biologicals) through a community pharmacy, rather
30 than through mail order, with any differential in
31 cost paid by such enrollees.

32 “(v) NOT REQUIRED TO ACCEPT INSURANCE
33 RISK.—The terms and conditions under clause (i)
34 may not require participating pharmacies to accept
35 insurance risk as a condition of participation.

36 “(2) USE OF STANDARDIZED TECHNOLOGY.—

28

1 “(A) IN GENERAL.—The PDP sponsor of a pre-
2 scription drug plan and an entity offering a MA-EFFS
3 Rx plan shall issue (and reissue, as appropriate) such
4 a card (or other technology) that may be used by an
5 enrollee to assure access to negotiated prices under sec-
6 tion 1860D–2(d) for the purchase of prescription drugs
7 for which coverage is not otherwise provided under the
8 plan.

9 “(B) STANDARDS.—

10 “(i) DEVELOPMENT.—The Administrator shall
11 provide for the development or utilization of uni-
12 form standards relating to a standardized format
13 for the card or other technology referred to in sub-
14 paragraph (A). Such standards shall be compatible
15 with standards established under part C of title XI.

16 “(ii) APPLICATION OF ADVISORY TASK
17 FORCE.—The advisory task force established under
18 subsection (d)(3)(B)(ii) shall provide recommenda-
19 tions to the Administrator under such subsection
20 regarding the standards developed under clause (i).

21 “(3) REQUIREMENTS ON DEVELOPMENT AND APPLICA-
22 TION OF FORMULARIES.—If a PDP sponsor of a prescrip-
23 tion drug plan or an entity offering a MA-EFFS Rx plan
24 uses a formulary, the following requirements must be met:

25 “(A) PHARMACY AND THERAPEUTIC (P&T) COM-
26 MITTEE.—The sponsor or entity must establish a phar-
27 macy and therapeutic committee that develops and re-
28 views the formulary. Such committee shall include at
29 least one practicing physician and at least one prac-
30 ticing pharmacist both with expertise in the care of el-
31 derly or disabled persons and a majority of its members
32 shall consist of individuals who are practicing physi-
33 cians or practicing pharmacists (or both).

34 “(B) FORMULARY DEVELOPMENT.—In developing
35 and reviewing the formulary, the committee shall—

36 “(i) base clinical decisions on the strength of
37 scientific evidence and standards of practice, in-

cluding assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information as the committee determines to be appropriate; and

“(ii) shall take into account whether including in the formulary particular covered outpatient drugs has therapeutic advantages in terms of safety and efficacy.

“(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES.—The formulary must include drugs within each therapeutic category and class of covered outpatient drugs (although not necessarily for all drugs within such categories and classes). In establishing such classes, the committee shall take into account the standards published in the United States Pharmacopeia-Drug Information. The committee shall make available to the enrollees under the plan through the Internet or otherwise the clinical bases for the coverage of any drug on the formulary.

“(D) PROVIDER AND PATIENT EDUCATION.—The committee shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

“(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY FOR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered outpatient drug from a formulary and any change in the preferred or tier cost-sharing status of such a drug shall take effect only after appropriate notice is made available to beneficiaries and physicians.

“(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the formulary, a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

“(G) GRIEVANCES AND APPEALS RELATING TO APPLICATION OF FORMULARIES.—For provisions relating

1 to grievances and appeals of coverage, see subsections
2 (e) and (f).

3 “(d) COST AND UTILIZATION MANAGEMENT; QUALITY AS-
4 SURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

5 “(1) IN GENERAL.—The PDP sponsor or entity offer-
6 ing a MA-EFFS Rx plan shall have in place, directly or
7 through appropriate arrangements, with respect to covered
8 outpatient drugs—

9 “(A) an effective cost and drug utilization man-
10 agement program, including medically appropriate in-
11 centives to use generic drugs and therapeutic inter-
12 change, when appropriate;

13 “(B) quality assurance measures and systems to
14 reduce medical errors and adverse drug interactions,
15 including side-effects, and improve medication use, in-
16 cluding a medication therapy management program de-
17 scribed in paragraph (2) and for years beginning with
18 2007, an electronic prescription program described in
19 paragraph (3); and

20 “(C) a program to control fraud, abuse, and
21 waste.

22 Nothing in this section shall be construed as impairing a
23 PDP sponsor or entity from utilizing cost management
24 tools (including differential payments) under all methods of
25 operation.

26 “(2) MEDICATION THERAPY MANAGEMENT PRO-
27 GRAM.—

28 “(A) IN GENERAL.—A medication therapy man-
29 agement program described in this paragraph is a pro-
30 gram of drug therapy management and medication ad-
31 ministration that may be furnished by a pharmacy pro-
32 vider and that is designed to assure, with respect to
33 beneficiaries at risk for potential medication problems,
34 such as beneficiaries with complex or chronic diseases
35 (such as diabetes, asthma, hypertension, and congestive
36 heart failure) or multiple prescriptions, that covered
37 outpatient drugs under the prescription drug plan are

1 appropriately used to optimize therapeutic outcomes
2 through improved medication use and reduce the risk
3 of adverse events, including adverse drug interactions.
4 Such programs may distinguish between services in am-
5 bulatory and institutional settings.

6 “(B) ELEMENTS.—Such program may include—

7 “(i) enhanced beneficiary understanding to
8 promote the appropriate use of medications by
9 beneficiaries and to reduce the risk of potential ad-
10 verse events associated with medications, through
11 beneficiary education, counseling, case manage-
12 ment, disease state management programs, and
13 other appropriate means;

14 “(ii) increased beneficiary adherence with pre-
15 scription medication regimens through medication
16 refill reminders, special packaging, and other com-
17 pliance programs and other appropriate means; and

18 “(iii) detection of patterns of overuse and
19 underuse of prescription drugs.

20 “(C) DEVELOPMENT OF PROGRAM IN COOPERA-
21 TION WITH LICENSED PHARMACISTS.—The program
22 shall be developed in cooperation with licensed and
23 practicing pharmacists and physicians.

24 “(D) CONSIDERATIONS IN PHARMACY FEES.—The
25 PDP sponsor of a prescription drug program and an
26 entity offering a MA-EFFS Rx plan shall take into ac-
27 count, in establishing fees for pharmacists and others
28 providing services under the medication therapy man-
29 agement program, the resources and time used in im-
30 plementing the program. Each such sponsor or entity
31 shall disclose to the Administrator upon request the
32 amount of any such management or dispensing fees.

33 “(3) ELECTRONIC PRESCRIPTION PROGRAM.—

34 “(A) IN GENERAL.—An electronic prescription
35 drug program described in this paragraph is a program
36 that includes at least the following components, con-

1 sistent with uniform standards established under sub-
2 paragraph (B):

3 “(i) ELECTRONIC TRANSMITTAL OF PRESCRIP-
4 TIONS.—Prescriptions must be written and trans-
5 mitted electronically (other than by facsimile), ex-
6 cept in emergency cases and other exceptional cir-
7 cumstances recognized by the Administrator.

8 “(ii) PROVISION OF INFORMATION TO PRE-
9 SCRIBING HEALTH CARE PROFESSIONAL.—The pro-
10 gram provides for the electronic transmittal to the
11 prescribing health care professional of information
12 that includes—

13 “(I) information (to the extent available
14 and feasible) on the drug or drugs being pre-
15 scribed for that patient and other information
16 relating to the medical history or condition of
17 the patient that may be relevant to the appro-
18 priate prescription for that patient;

19 “(II) cost-effective alternatives (if any) for
20 the use of the drug prescribed; and

21 “(III) information on the drugs included
22 in the applicable formulary.

23 To the extent feasible, such program shall permit
24 the prescribing health care professional to provide
25 (and be provided) related information on an inter-
26 active, real-time basis.

27 “(B) STANDARDS.—

28 “(i) DEVELOPMENT.—The Administrator shall
29 provide for the development of uniform standards
30 relating to the electronic prescription drug program
31 described in subparagraph (A). Such standards
32 shall be compatible with standards established
33 under part C of title XI.

34 “(ii) ADVISORY TASK FORCE.—In developing
35 such standards and the standards described in sub-
36 section (c)(2)(B)(i) the Administrator shall estab-
37 lish a task force that includes representatives of

33

1 physicians, hospitals, pharmacies, beneficiaries,
2 pharmacy benefit managers, individuals with exper-
3 tise in information technology, and pharmacy ben-
4 efit experts of the Departments of Veterans Affairs
5 and Defense and other appropriate Federal agen-
6 cies to provide recommendations to the Adminis-
7 trator on such standards, including recommenda-
8 tions relating to the following:

9 “(I) The range of available computerized
10 prescribing software and hardware and their
11 costs to develop and implement.

12 “(II) The extent to which such standards
13 and systems reduce medication errors and can
14 be readily implemented by physicians, phar-
15 macies, and hospitals.

16 “(III) Efforts to develop uniform stand-
17 ards and a common software platform for the
18 secure electronic communication of medication
19 history, eligibility, benefit, and prescription in-
20 formation.

21 “(IV) Efforts to develop and promote uni-
22 versal connectivity and interoperability for the
23 secure electronic exchange of such information.

24 “(V) The cost of implementing such sys-
25 tems in the range of hospital and physician of-
26 fice settings and pharmacies, including hard-
27 ware, software, and training costs.

28 “(VI) Implementation issues as they relate
29 to part C of title XI, and current Federal and
30 State prescribing laws and regulations and
31 their impact on implementation of computer-
32 ized prescribing.

33 “(iii) DEADLINES.—

34 “(I) The Administrator shall constitute
35 the task force under clause (ii) by not later
36 than April 1, 2004.

1 “(II) Such task force shall submit rec-
2 ommendations to Administrator by not later
3 than January 1, 2005.

4 “(III) The Administrator shall provide for
5 the development and promulgation, by not later
6 than January 1, 2006, of national standards
7 relating to the electronic prescription drug pro-
8 gram described in clause (ii). Such standards
9 shall be issued by a standards organization ac-
10 credited by the American National Standards
11 Institute (ANSI) and shall be compatible with
12 standards established under part C of title XI.

13 “(4) TREATMENT OF ACCREDITATION.—Section
14 1852(e)(4) (relating to treatment of accreditation) shall
15 apply to prescription drug plans under this part with re-
16 spect to the following requirements, in the same manner as
17 they apply to plans under part C with respect to the re-
18 quirements described in a clause of section 1852(e)(4)(B):

19 “(A) Paragraph (1) (including quality assurance),
20 including medication therapy management program
21 under paragraph (2).

22 “(B) Subsection (c)(1) (relating to access to cov-
23 ered benefits).

24 “(C) Subsection (g) (relating to confidentiality and
25 accuracy of enrollee records).

26 “(5) PUBLIC DISCLOSURE OF PHARMACEUTICAL
27 PRICES FOR EQUIVALENT DRUGS.—Each PDP sponsor and
28 each entity offering a MA-EFFS Rx plan shall provide that
29 each pharmacy or other dispenser that arranges for the dis-
30 pensing of a covered outpatient drug shall inform the bene-
31 ficiary at the time of purchase of the drug of any differen-
32 tial between the price of the prescribed drug to the enrollee
33 and the price of the lowest cost available generic drug cov-
34 ered under the plan that is therapeutically equivalent and
35 bioequivalent.

36 “(e) GRIEVANCE MECHANISM, COVERAGE DETERMINA-
37 TIONS, AND RECONSIDERATIONS.—

1 “(1) IN GENERAL.—Each PDP sponsor shall provide
2 meaningful procedures for hearing and resolving grievances
3 between the organization (including any entity or individual
4 through which the sponsor provides covered benefits) and
5 enrollees with prescription drug plans of the sponsor under
6 this part in accordance with section 1852(f).

7 “(2) APPLICATION OF COVERAGE DETERMINATION
8 AND RECONSIDERATION PROVISIONS.—A PDP sponsor
9 shall meet the requirements of paragraphs (1) through (3)
10 of section 1852(g) with respect to covered benefits under
11 the prescription drug plan it offers under this part in the
12 same manner as such requirements apply to an organiza-
13 tion with respect to benefits it offers under a plan under
14 part C.

15 “(3) REQUEST FOR REVIEW OF TIERED FORMULARY
16 DETERMINATIONS.—In the case of a prescription drug plan
17 offered by a PDP sponsor or a MA-EFFS Rx plan that
18 provides for tiered cost-sharing for drugs included within a
19 formulary and provides lower cost-sharing for preferred
20 drugs included within the formulary, an individual who is
21 enrolled in the plan may request coverage of a nonpreferred
22 drug under the terms applicable for preferred drugs if the
23 prescribing physician determines that the preferred drug
24 for treatment of the same condition either would not be as
25 effective for the individual or would have adverse effects for
26 the individual or both.

27 “(f) APPEALS.—

28 “(1) IN GENERAL.—Subject to paragraph (2), a PDP
29 sponsor shall meet the requirements of paragraphs (4) and
30 (5) of section 1852(g) with respect to drugs (including a
31 determination related to the application of tiered cost-shar-
32 ing described in subsection (e)(3)) in the same manner as
33 such requirements apply to an organization with respect to
34 benefits it offers under a plan under part C.

35 “(2) FORMULARY DETERMINATIONS.—An individual
36 who is enrolled in a prescription drug plan offered by a
37 PDP sponsor or in a MA-EFFS Rx plan may appeal to ob-

1 tain coverage for a covered outpatient drug that is not on
2 a formulary of the sponsor or entity offering the plan if the
3 prescribing physician determines that the formulary drug
4 for treatment of the same condition either would not be as
5 effective for the individual or would have adverse effects for
6 the individual or both.

7 “(g) CONFIDENTIALITY AND ACCURACY OF ENROLLEE
8 RECORDS.—A PDP sponsor that offers a prescription drug
9 plan shall meet the requirements of section 1852(h) with re-
10 spect to enrollees under the plan in the same manner as such
11 requirements apply to an organization with respect to enrollees
12 under part C. A PDP sponsor shall be treated as a covered en-
13 tity for purposes of the provisions of subpart E of part 164 of
14 title 45, Code of Federal Regulations, adopted pursuant to the
15 authority of the Secretary under section 264(c) of the Health
16 Insurance Portability and Accountability Act of 1996 (42 U.S.
17 C. 1320d-2 note).

18 **“SEC. 1860D-4. REQUIREMENTS FOR AND CONTRACTS**
19 **WITH PRESCRIPTION DRUG PLAN (PDP)**
20 **SPONSORS.**

21 “(a) GENERAL REQUIREMENTS.—Each PDP sponsor of a
22 prescription drug plan shall meet the following requirements:

23 “(1) LICENSURE.—Subject to subsection (c), the spon-
24 sor is organized and licensed under State law as a risk-
25 bearing entity eligible to offer health insurance or health
26 benefits coverage in each State in which it offers a pre-
27 scription drug plan.

28 “(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUB-
29 SIDIZED COVERAGE.—

30 “(A) IN GENERAL.—Subject to subparagraph (B)
31 and section 1860D-5(d)(2), the entity assumes full fi-
32 nancial risk on a prospective basis for qualified pre-
33 scription drug coverage that it offers under a prescrip-
34 tion drug plan and that is not covered under section
35 1860D-8.

1 “(B) REINSURANCE PERMITTED.—The entity may
2 obtain insurance or make other arrangements for the
3 cost of coverage provided to any enrollee.

4 “(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the
5 case of a sponsor that is not described in paragraph (1),
6 the sponsor shall meet solvency standards established by
7 the Administrator under subsection (d).

8 “(b) CONTRACT REQUIREMENTS.—

9 “(1) IN GENERAL.—The Administrator shall not per-
10 mit the election under section 1860D–1 of a prescription
11 drug plan offered by a PDP sponsor under this part, and
12 the sponsor shall not be eligible for payments under section
13 1860D–7 or 1860D–8, unless the Administrator has en-
14 tered into a contract under this subsection with the sponsor
15 with respect to the offering of such plan. Such a contract
16 with a sponsor may cover more than one prescription drug
17 plan. Such contract shall provide that the sponsor agrees
18 to comply with the applicable requirements and standards
19 of this part and the terms and conditions of payment as
20 provided for in this part.

21 “(2) NEGOTIATION REGARDING TERMS AND CONDI-
22 TIONS.—The Administrator shall have the same authority
23 to negotiate the terms and conditions of prescription drug
24 plans under this part as the Director of the Office of Per-
25 sonnel Management has with respect to health benefits
26 plans under chapter 89 of title 5, United States Code. In
27 negotiating the terms and conditions regarding premiums
28 for which information is submitted under section 1860D–
29 6(a)(2), the Administrator shall take into account the sub-
30 sidy payments under section 1860D–8.

31 “(3) INCORPORATION OF CERTAIN MEDICARE ADVAN-
32 TAGE CONTRACT REQUIREMENTS.—The following provi-
33 sions of section 1857 shall apply, subject to subsection
34 (c)(5), to contracts under this section in the same manner
35 as they apply to contracts under section 1857(a):

36 “(A) MINIMUM ENROLLMENT.—Paragraphs (1)
37 and (3) of section 1857(b).

38

1 “(B) CONTRACT PERIOD AND EFFECTIVENESS.—
2 Paragraphs (1) through (3) and (5) of section 1857(c).

3 “(C) PROTECTIONS AGAINST FRAUD AND BENE-
4 FICIARY PROTECTIONS.—Section 1857(d).

5 “(D) ADDITIONAL CONTRACT TERMS.—Section
6 1857(e); except that in applying section 1857(e)(2)
7 under this part—

8 “(i) such section shall be applied separately to
9 costs relating to this part (from costs under part
10 C and part E);

11 “(ii) in no case shall the amount of the fee es-
12 tablished under this subparagraph for a plan ex-
13 ceed 20 percent of the maximum amount of the fee
14 that may be established under subparagraph (B) of
15 such section; and

16 “(iii) no fees shall be applied under this sub-
17 paragraph with respect to MA-EFFS Rx plans.

18 “(E) INTERMEDIATE SANCTIONS.—Section
19 1857(g).

20 “(F) PROCEDURES FOR TERMINATION.—Section
21 1857(h).

22 “(4) RULES OF APPLICATION FOR INTERMEDIATE
23 SANCTIONS.—In applying paragraph (3)(E)—

24 “(A) the reference in section 1857(g)(1)(B) to sec-
25 tion 1854 is deemed a reference to this part; and

26 “(B) the reference in section 1857(g)(1)(F) to sec-
27 tion 1852(k)(2)(A)(ii) shall not be applied.

28 “(5) SERVICE AREA REQUIREMENT.—For purposes of
29 this part, the Administrator shall designate at least 10
30 areas covering the entire United States and to the extent
31 practicable shall be consistent with EFFS regions estab-
32 lished under section 1860E-1(a)(2).

33 “(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND
34 CHOICE.—

35 “(1) IN GENERAL.—In the case of an entity that seeks
36 to offer a prescription drug plan in a State, the Adminis-
37 trator shall waive the requirement of subsection (a)(1) that

1 the entity be licensed in that State if the Administrator de-
2 termines, based on the application and other evidence pre-
3 sented to the Administrator, that any of the grounds for
4 approval of the application described in paragraph (2) have
5 been met.

6 “(2) GROUNDS FOR APPROVAL.—The grounds for ap-
7 proval under this paragraph are the grounds for approval
8 described in subparagraph (B), (C), and (D) of section
9 1855(a)(2), and also include the application by a State of
10 any grounds other than those required under Federal law.

11 “(3) APPLICATION OF WAIVER PROCEDURES.—With
12 respect to an application for a waiver (or a waiver granted)
13 under this subsection, the provisions of subparagraphs (E),
14 (F), and (G) of section 1855(a)(2) shall apply.

15 “(4) LICENSURE DOES NOT SUBSTITUTE FOR OR CON-
16 STITUTE CERTIFICATION.—The fact that an entity is li-
17 censed in accordance with subsection (a)(1) does not deem
18 the entity to meet other requirements imposed under this
19 part for a PDP sponsor.

20 “(5) REFERENCES TO CERTAIN PROVISIONS.—For
21 purposes of this subsection, in applying provisions of sec-
22 tion 1855(a)(2) under this subsection to prescription drug
23 plans and PDP sponsors—

24 “(A) any reference to a waiver application under
25 section 1855 shall be treated as a reference to a waiver
26 application under paragraph (1); and

27 “(B) any reference to solvency standards shall be
28 treated as a reference to solvency standards established
29 under subsection (d).

30 “(d) SOLVENCY STANDARDS FOR NON-LICENSED SPON-
31 SORS.—

32 “(1) ESTABLISHMENT.—The Administrator shall es-
33 tablish, by not later than October 1, 2004, financial sol-
34 vency and capital adequacy standards that an entity that
35 does not meet the requirements of subsection (a)(1) must
36 meet to qualify as a PDP sponsor under this part.

1 “(2) COMPLIANCE WITH STANDARDS.—Each PDP
2 sponsor that is not licensed by a State under subsection
3 (a)(1) and for which a waiver application has been ap-
4 proved under subsection (c) shall meet solvency and capital
5 adequacy standards established under paragraph (1). The
6 Administrator shall establish certification procedures for
7 such PDP sponsors with respect to such solvency standards
8 in the manner described in section 1855(c)(2).

9 “(e) RELATION TO STATE LAWS.—

10 “(1) IN GENERAL.—The standards established under
11 this part shall supersede any State law or regulation (other
12 than State licensing laws or State laws relating to plan sol-
13 vency, except as provided in subsection (d)) with respect to
14 prescription drug plans which are offered by PDP sponsors
15 under this part.

16 “(2) PROHIBITION OF STATE IMPOSITION OF PREMIUM
17 TAXES.—No State may impose a premium tax or similar
18 tax with respect to premiums paid to PDP sponsors for
19 prescription drug plans under this part, or with respect to
20 any payments made to such a sponsor by the Administrator
21 under this part.

22 **“SEC. 1860D-5. PROCESS FOR BENEFICIARIES TO SE-**
23 **LECT QUALIFIED PRESCRIPTION DRUG COV-**
24 **ERAGE.**

25 “(a) IN GENERAL.—The Administrator shall establish a
26 process for the selection of the prescription drug plan or MA-
27 EFFS Rx plan through which eligible individuals elect qualified
28 prescription drug coverage under this part.

29 “(b) ELEMENTS.—Such process shall include the fol-
30 lowing:

31 “(1) Annual, coordinated election periods, in which
32 such individuals can change the qualifying plans through
33 which they obtain coverage, in accordance with section
34 1860D-1(b)(2).

35 “(2) Active dissemination of information to promote
36 an informed selection among qualifying plans based upon
37 price, quality, and other features, in the manner described

1 in (and in coordination with) section 1851(d), including the
2 provision of annual comparative information, maintenance
3 of a toll-free hotline, and the use of non-Federal entities.

4 “(3) Coordination of elections through filing with the
5 entity offering a MA-EFFS Rx plan or a PDP sponsor, in
6 the manner described in (and in coordination with) section
7 1851(c)(2).

8 “(4) Informing each enrollee before the beginning of
9 each year of the annual out-of-pocket threshold applicable
10 to the enrollee for that year under section 1860D-2(b)(4)
11 at such time.

12 “(c) MA-EFFS Rx ENROLLEE MAY ONLY OBTAIN BENE-
13 FITS THROUGH THE PLAN.—An individual who is enrolled
14 under a MA-EFFS Rx plan may only elect to receive qualified
15 prescription drug coverage under this part through such plan.

16 “(d) ASSURING ACCESS TO A CHOICE OF QUALIFIED PRE-
17SCRIPTION DRUG COVERAGE.—

18 “(1) CHOICE OF AT LEAST TWO PLANS IN EACH
19 AREA.—

20 “(A) IN GENERAL.—The Administrator shall as-
21 sure that each individual who is entitled to benefits
22 under part A or enrolled under part B and who is re-
23 siding in an area in the United States has available,
24 consistent with subparagraph (B), a choice of enroll-
25 ment in at least two qualifying plans (as defined in
26 paragraph (5)) in the area in which the individual re-
27 sides, at least one of which is a prescription drug plan.

28 “(B) REQUIREMENT FOR DIFFERENT PLAN SPON-
29 SORS.—The requirement in subparagraph (A) is not
30 satisfied with respect to an area if only one PDP spon-
31 sor or one entity that offers a MA-EFFS Rx plan of-
32 fers all the qualifying plans in the area.

33 “(2) GUARANTEEING ACCESS TO COVERAGE.—In order
34 to assure access under paragraph (1) and consistent with
35 paragraph (3), the Administrator may provide partial un-
36 derwriting of risk for a PDP sponsor to expand the service
37 area under an existing prescription drug plan to adjoining

1 or additional areas or to establish such a plan (including
2 offering such a plan on a regional or nationwide basis), but
3 only so long as (and to the extent) necessary to assure the
4 access guaranteed under paragraph (1).

5 “(3) LIMITATION ON AUTHORITY.—In exercising au-
6 thority under this subsection, the Administrator—

7 “(A) shall not provide for the full underwriting of
8 financial risk for any PDP sponsor; and

9 “(B) shall seek to maximize the assumption of fi-
10 nancial risk by PDP sponsors or entities offering a
11 MA-EFFS Rx plan.

12 “(4) REPORTS.—The Administrator shall, in each an-
13 nual report to Congress under section 1809(f), include in-
14 formation on the exercise of authority under this sub-
15 section. The Administrator also shall include such rec-
16 ommendations as may be appropriate to minimize the exer-
17 cise of such authority, including minimizing the assumption
18 of financial risk.

19 “(5) QUALIFYING PLAN DEFINED.—For purposes of
20 this subsection, the term ‘qualifying plan’ means a pre-
21 scription drug plan or a MA-EFFS Rx plan.

22 **“SEC. 1860D-6. SUBMISSION OF BIDS AND PREMIUMS.**

23 “(a) SUBMISSION OF BIDS, PREMIUMS, AND RELATED IN-
24 FORMATION.—

25 “(1) IN GENERAL.—Each PDP sponsor shall submit
26 to the Administrator the information described in para-
27 graph (2) in the same manner as information is submitted
28 by an organization under section 1854(a)(1).

29 “(2) INFORMATION SUBMITTED.—The information de-
30 scribed in this paragraph is the following:

31 “(A) COVERAGE PROVIDED.—Information on the
32 qualified prescription drug coverage to be provided.

33 “(B) ACTUARIAL VALUE.—Information on the ac-
34 tuarial value of the coverage.

35 “(C) BID AND PREMIUM.—Information on the bid
36 and the premium for the coverage, including an actu-
37 arial certification of—

1 “(i) the actuarial basis for such bid and pre-
2 mium;

3 “(ii) the portion of such bid and premium at-
4 tributable to benefits in excess of standard cov-
5 erage;

6 “(iii) the reduction in such bid resulting from
7 the reinsurance subsidy payments provided under
8 section 1860D–8(a)(2); and

9 “(iv) the reduction in such premium resulting
10 from the direct and reinsurance subsidy payments
11 provided under section 1860D–8.

12 “(D) ADDITIONAL INFORMATION.—Such other in-
13 formation as the Administrator may require to carry
14 out this part.

15 “(3) REVIEW OF INFORMATION; NEGOTIATION AND
16 APPROVAL OF PREMIUMS.—

17 “(A) IN GENERAL.—Subject to subparagraph (B),
18 the Administrator shall review the information filed
19 under paragraph (2) for the purpose of conducting ne-
20 gotiations under section 1860D–4(b)(2) (relating to
21 using OPM-like authority under the FEHBP). The Ad-
22 ministrator, using the information provided (including
23 the actuarial certification under paragraph (2)(C))
24 shall approve the premium submitted under this sub-
25 section only if the premium accurately reflects both (i)
26 the actuarial value of the benefits provided, and (ii) the
27 73 percent average subsidy provided under section
28 1860D–8 for the standard benefit. The Administrator
29 shall apply actuarial principles to approval of a pre-
30 mium under this part in a manner similar to the man-
31 ner in which those principles are applied in establishing
32 the monthly part B premium under section 1839.

33 “(B) EXCEPTION.—In the case of a plan described
34 in section 1851(a)(2)(C), the provisions of subpara-
35 graph (A) shall not apply and the provisions of para-
36 graph (5)(B) of section 1854(a), prohibiting the review,
37 approval, or disapproval of amounts described in such

1 paragraph, shall apply to the negotiation and rejection
2 of the monthly bid amounts and proportion referred to
3 in subparagraph (A).

4 “(b) UNIFORM BID AND PREMIUM.—

5 “(1) IN GENERAL.—The bid and premium for a pre-
6 scription drug plan under this section may not vary among
7 enrollees in the plan in the same service area.

8 “(2) CONSTRUCTION.—Nothing in paragraph (1) shall
9 be construed as preventing the imposition of a late enroll-
10 ment penalty under section 1860D–1(c)(2)(B).

11 “(c) COLLECTION.—

12 “(1) BENEFICIARY’S OPTION OF PAYMENT THROUGH
13 WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE
14 OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In ac-
15 cordance with regulations, a PDP sponsor shall permit
16 each enrollee, at the enrollee’s option, to make payment of
17 premiums under this part to the sponsor through with-
18 holding from benefit payments in the manner provided
19 under section 1840 with respect to monthly premiums
20 under section 1839 or through an electronic funds transfer
21 mechanism (such as automatic charges of an account at a
22 financial institution or a credit or debit card account) or
23 otherwise. All premium payments under this paragraph
24 shall be credited to the Medicare Prescription Drug Trust
25 Fund.

26 “(2) OFFSETTING.—Reductions in premiums for cov-
27 erage under parts A and B as a result of a selection of a
28 MA-EFFS Rx plan may be used to reduce the premium
29 otherwise imposed under paragraph (1).

30 “(d) ACCEPTANCE OF REFERENCE PREMIUM AMOUNT AS
31 FULL PREMIUM FOR SUBSIDIZED LOW-INCOME INDIVIDUALS
32 IF NO STANDARD (OR EQUIVALENT) COVERAGE IN AN AREA.—

33 “(1) IN GENERAL.—If there is no standard prescrip-
34 tion drug coverage (as defined in paragraph (2)) offered in
35 an area, in the case of an individual who is eligible for a
36 premium subsidy under section 1860D–7 and resides in the
37 area, the PDP sponsor of any prescription drug plan of-

1 fered in the area (and any entity offering a MA-EFFS Rx
2 plan in the area) shall accept the reference premium
3 amount (under paragraph (3)) as payment in full for the
4 premium charge for qualified prescription drug coverage.

5 “(2) STANDARD PRESCRIPTION DRUG COVERAGE DE-
6 FINED.—For purposes of this subsection, the term ‘stand-
7 ard prescription drug coverage’ means qualified prescrip-
8 tion drug coverage that is standard coverage or that has
9 an actuarial value equivalent to the actuarial value for
10 standard coverage.

11 “(3) REFERENCE PREMIUM AMOUNT DEFINED.—For
12 purposes of this subsection, the term ‘reference premium
13 amount’ means, with respect to qualified prescription drug
14 coverage offered under—

15 “(A) a prescription drug plan that—

16 “(i) provides standard coverage (or alternative
17 prescription drug coverage the actuarial value is
18 equivalent to that of standard coverage), the plan’s
19 PDP premium; or

20 “(ii) provides alternative prescription drug
21 coverage the actuarial value of which is greater
22 than that of standard coverage, the plan’s PDP
23 premium multiplied by the ratio of (I) the actuarial
24 value of standard coverage, to (II) the actuarial
25 value of the alternative coverage;

26 “(B) an EFFS plan, the EFFS monthly prescrip-
27 tion drug beneficiary premium (as defined in section
28 1860E-4(a)(3)(B)); or

29 “(C) a Medicare Advantage, the Medicare Advan-
30 tage monthly prescription drug beneficiary premium (as
31 defined in section 1854(b)(2)(B)).

32 For purposes of subparagraph (A), the term ‘PDP pre-
33 mium’ means, with respect to a prescription drug plan, the
34 premium amount for enrollment under the plan under this
35 part (determined without regard to any low-income subsidy
36 under section 1860D-7 or any late enrollment penalty
37 under section 1860D-1(c)(2)(B)).

1 **“SEC. 1860D-7. PREMIUM AND COST-SHARING SUBSIDIES**
2 **FOR LOW-INCOME INDIVIDUALS.**

3 “(a) INCOME-RELATED SUBSIDIES FOR INDIVIDUALS
4 WITH INCOME BELOW 150 PERCENT OF FEDERAL POVERTY
5 LEVEL.—

6 “(1) FULL PREMIUM SUBSIDY AND REDUCTION OF
7 COST-SHARING FOR INDIVIDUALS WITH INCOME BELOW 135
8 PERCENT OF FEDERAL POVERTY LEVEL.—In the case of a
9 subsidy eligible individual (as defined in paragraph (4))
10 who is determined to have income that does not exceed 135
11 percent of the Federal poverty level, the individual is enti-
12 tled under this section—

13 “(A) to an income-related premium subsidy equal
14 to 100 percent of the amount described in subsection
15 (b)(1); and

16 “(B) subject to subsection (c), to the substitution
17 for the beneficiary cost-sharing described in paragraphs
18 (1) and (2) of section 1860D-2(b) (up to the initial
19 coverage limit specified in paragraph (3) of such sec-
20 tion) of amounts that do not exceed \$2 for a multiple
21 source or generic drug (as described in section
22 1927(k)(7)(A)) and \$5 for a non-preferred drug.

23 “(2) SLIDING SCALE PREMIUM SUBSIDY FOR INDIVID-
24 UALS WITH INCOME ABOVE 135, BUT BELOW 150 PERCENT,
25 OF FEDERAL POVERTY LEVEL.—In the case of a subsidy el-
26 igible individual who is determined to have income that ex-
27 ceeds 135 percent, but does not exceed 150 percent, of the
28 Federal poverty level, the individual is entitled under this
29 section to an income-related premium subsidy determined
30 on a linear sliding scale ranging from 100 percent of the
31 amount described in subsection (b)(1) for individuals with
32 incomes at 135 percent of such level to 0 percent of such
33 amount for individuals with incomes at 150 percent of such
34 level.

35 “(3) CONSTRUCTION.—Nothing in this section shall be
36 construed as preventing a PDP sponsor or entity offering

1 a MA-EFFS Rx plan from reducing to 0 the cost-sharing
2 otherwise applicable to generic drugs.

3 “(4) DETERMINATION OF ELIGIBILITY.—

4 “(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—
5 For purposes of this section, subject to subparagraph
6 (D), the term ‘subsidy eligible individual’ means an in-
7 dividual who—

8 “(i) is eligible to elect, and has elected, to ob-
9 tain qualified prescription drug coverage under this
10 part;

11 “(ii) has income below 150 percent of the Fed-
12 eral poverty line; and

13 “(iii) meets the resources requirement de-
14 scribed in subparagraph (D) .

15 “(B) DETERMINATIONS.—The determination of
16 whether an individual residing in a State is a subsidy
17 eligible individual and the amount of such individual’s
18 income shall be determined under the State medicaid
19 plan for the State under section 1935(a) or by the So-
20 cial Security Administration. In the case of a State
21 that does not operate such a medicaid plan (either
22 under title XIX or under a statewide waiver granted
23 under section 1115), such determination shall be made
24 under arrangements made by the Administrator. There
25 are authorized to be appropriated to the Social Security
26 Administration such sums as may be necessary for the
27 determination of eligibility under this subparagraph.

28 “(C) INCOME DETERMINATIONS.—For purposes of
29 applying this section—

30 “(i) income shall be determined in the manner
31 described in section 1905(p)(1)(B); and

32 “(ii) the term ‘Federal poverty line’ means the
33 official poverty line (as defined by the Office of
34 Management and Budget, and revised annually in
35 accordance with section 673(2) of the Omnibus
36 Budget Reconciliation Act of 1981) applicable to a
37 family of the size involved.

1 “(D) RESOURCE STANDARD APPLIED TO BE
2 BASED ON TWICE SSI RESOURCE STANDARD.—The re-
3 source requirement of this subparagraph is that an in-
4 dividual’s resources (as determined under section 1613
5 for purposes of the supplemental security income pro-
6 gram) do not exceed—

7 “(i) for 2006 twice the maximum amount of
8 resources that an individual may have and obtain
9 benefits under that program; and

10 “(ii) for a subsequent year the resource limita-
11 tion established under this clause for the previous
12 year increased by the annual percentage increase in
13 the consumer price index (all items; U.S. city aver-
14 age) as of September of such previous year.

15 Any resource limitation established under clause (ii)
16 that is not a multiple of \$10 shall be rounded to the
17 nearest multiple of \$10.

18 “(E) TREATMENT OF TERRITORIAL RESIDENTS.—
19 In the case of an individual who is not a resident of
20 the 50 States or the District of Columbia, the indi-
21 vidual is not eligible to be a subsidy eligible individual
22 but may be eligible for financial assistance with pre-
23 scription drug expenses under section 1935(e).

24 “(F) TREATMENT OF CONFORMING MEDIGAP
25 POLICIES.—For purposes of this section, the term
26 ‘qualified prescription drug coverage’ includes a medi-
27 care supplemental policy described in section 1860D-
28 8(b)(4).

29 “(5) INDEXING DOLLAR AMOUNTS.—

30 “(A) FOR 2007.—The dollar amounts applied
31 under paragraphs (1)(B) for 2007 shall be the dollar
32 amounts specified in such paragraph increased by the
33 annual percentage increase described in section
34 1860D-2(b)(5) for 2007.

35 “(B) FOR SUBSEQUENT YEARS.—The dollar
36 amounts applied under paragraph (1)(B) for a year
37 after 2007 shall be the amounts (under this paragraph)

1 applied under paragraph (1)(B) for the preceding year
2 increased by the annual percentage increase described
3 in section 1860D-2(b)(5) (relating to growth in medi-
4 care prescription drug costs per beneficiary) for the
5 year involved.

6 “(b) PREMIUM SUBSIDY AMOUNT.—

7 “(1) IN GENERAL.—The premium subsidy amount de-
8 scribed in this subsection for an individual residing in an
9 area is the benchmark premium amount (as defined in
10 paragraph (2)) for qualified prescription drug coverage of-
11 fered by the prescription drug plan or the MA-EFFS Rx
12 plan in which the individual is enrolled.

13 “(2) BENCHMARK PREMIUM AMOUNT DEFINED.—For
14 purposes of this subsection, the term ‘benchmark premium
15 amount’ means, with respect to qualified prescription drug
16 coverage offered under—

17 “(A) a prescription drug plan that—

18 “(i) provides standard coverage (or alternative
19 prescription drug coverage the actuarial value is
20 equivalent to that of standard coverage), the pre-
21 mium amount for enrollment under the plan under
22 this part (determined without regard to any sub-
23 sidy under this section or any late enrollment pen-
24 alty under section 1860D-1(c)(2)(B)); or

25 “(ii) provides alternative prescription drug
26 coverage the actuarial value of which is greater
27 than that of standard coverage, the premium
28 amount described in clause (i) multiplied by the
29 ratio of (I) the actuarial value of standard cov-
30 erage, to (II) the actuarial value of the alternative
31 coverage; or

32 “(B) a MA-EFFS Rx plan, the portion of the pre-
33 mium amount that is attributable to statutory drug
34 benefits (described in section 1853(a)(1)(A)(ii)(II)).

35 “(c) RULES IN APPLYING COST-SHARING SUBSIDIES.—

36 “(1) IN GENERAL.—In applying subsection (a)(1)(B),
37 nothing in this part shall be construed as preventing a plan

1 or provider from waiving or reducing the amount of cost-
2 sharing otherwise applicable.

3 “(2) LIMITATION ON CHARGES.—In the case of an in-
4 dividual receiving cost-sharing subsidies under subsection
5 (a)(1)(B), the PDP sponsor or entity offering a MA-EFFS
6 Rx plan may not charge more than \$5 per prescription.

7 “(3) APPLICATION OF INDEXING RULES.—The provi-
8 sions of subsection (a)(5) shall apply to the dollar amount
9 specified in paragraph (2) in the same manner as they
10 apply to the dollar amounts specified in subsections
11 (a)(1)(B).

12 “(d) ADMINISTRATION OF SUBSIDY PROGRAM.—The Ad-
13 ministrator shall provide a process whereby, in the case of an
14 individual who is determined to be a subsidy eligible individual
15 and who is enrolled in prescription drug plan or is enrolled in
16 a MA-EFFS Rx plan—

17 “(1) the Administrator provides for a notification of
18 the PDP sponsor or the entity offering the MA-EFFS Rx
19 plan involved that the individual is eligible for a subsidy
20 and the amount of the subsidy under subsection (a);

21 “(2) the sponsor or entity involved reduces the pre-
22 miums or cost-sharing otherwise imposed by the amount of
23 the applicable subsidy and submits to the Administrator in-
24 formation on the amount of such reduction; and

25 “(3) the Administrator periodically and on a timely
26 basis reimburses the sponsor or entity for the amount of
27 such reductions.

28 The reimbursement under paragraph (3) with respect to cost-
29 sharing subsidies may be computed on a capitated basis, taking
30 into account the actuarial value of the subsidies and with ap-
31 propriate adjustments to reflect differences in the risks actually
32 involved.

33 “(e) RELATION TO MEDICAID PROGRAM.—

34 “(1) IN GENERAL.—For provisions providing for eligi-
35 bility determinations, and additional financing, under the
36 medicaid program, see section 1935.

1 “(2) MEDICAID PROVIDING WRAP AROUND BENE-
2 FITS.—The coverage provided under this part is primary
3 payor to benefits for prescribed drugs provided under the
4 medicaid program under title XIX consistent with section
5 1935(d)(1).

6 “(3) COORDINATION.—The Administrator shall de-
7 velop and implement a plan for the coordination of pre-
8 scription drug benefits under this part with the benefits
9 provided under the medicaid program under title XIX, with
10 particular attention to insuring coordination of payments
11 and prevention of fraud and abuse. In developing and im-
12 plementing such plan, the Administrator shall involve the
13 Secretary, the States, the data processing industry, phar-
14 macists, and pharmaceutical manufacturers, and other ex-
15 perts.

16 **“SEC. 1860D-8. SUBSIDIES FOR ALL MEDICARE BENE-**
17 **FICIARIES FOR QUALIFIED PRESCRIPTION**
18 **DRUG COVERAGE.**

19 “(a) SUBSIDY PAYMENT.—In order to reduce premium
20 levels applicable to qualified prescription drug coverage for all
21 medicare beneficiaries consistent with an overall subsidy level
22 of 73 percent, to reduce adverse selection among prescription
23 drug plans and MA-EFFS Rx plans, and to promote the par-
24 ticipation of PDP sponsors under this part, the Administrator
25 shall provide in accordance with this section for payment to a
26 qualifying entity (as defined in subsection (b)) of the following
27 subsidies:

28 “(1) DIRECT SUBSIDY.—In the case of an enrollee en-
29 rolled for a month in a prescription drug plan or a MA-
30 EFFS Rx plan, a direct subsidy equal to 43 percent of the
31 national average monthly bid amount (computed under sub-
32 section (g)) for that month.

33 “(2) SUBSIDY THROUGH REINSURANCE.—In the case
34 of an enrollee enrolled for a month in a prescription drug
35 plan or a MA-EFFS Rx plan, the reinsurance payment
36 amount (as defined in subsection (c)), which in the aggre-
37 gate is 30 percent of the total payments made by qualifying

1 entities for standard coverage under the respective plan, for
2 excess costs incurred in providing qualified prescription
3 drug coverage—

4 “(A) for enrollees with a prescription drug plan
5 under this part; and

6 “(B) for enrollees with a MA-EFFS Rx plan.

7 “(3) EMPLOYER AND UNION FLEXIBILITY.—In the
8 case of an individual who is a participant or beneficiary in
9 a qualified retiree prescription drug plan (as defined in
10 subsection (f)(1)) and who is not enrolled in a prescription
11 drug plan or in a MA-EFFS Rx plan, the special subsidy
12 payments under subsection (f)(3).

13 This section constitutes budget authority in advance of appro-
14 priations Acts and represents the obligation of the Adminis-
15 trator to provide for the payment of amounts provided under
16 this section. In applying the percentages under paragraphs (1)
17 and (2), there shall be taken into account under the respective
18 paragraphs the portion of the employer and union special sub-
19 sidy payments under subsection (f)(3) that reflect payments
20 that would have been made under the respective paragraphs if
21 such paragraphs had applied to qualified retiree prescription
22 drug plans instead of paragraph (3).

23 “(b) QUALIFYING ENTITY DEFINED.—For purposes of
24 this section, the term ‘qualifying entity’ means any of the fol-
25 lowing that has entered into an agreement with the Adminis-
26 trator to provide the Administrator with such information as
27 may be required to carry out this section:

28 “(1) A PDP sponsor offering a prescription drug plan
29 under this part.

30 “(2) An entity that offers a MA-EFFS Rx plan.

31 “(3) The sponsor of a qualified retiree prescription
32 drug plan (as defined in subsection (f)).

33 “(c) REINSURANCE PAYMENT AMOUNT.—

34 “(1) IN GENERAL.—Subject to subsection (d)(1)(B)
35 and paragraph (4), the reinsurance payment amount under
36 this subsection for a qualifying covered individual (as de-

1 fined in paragraph (5)) for a coverage year (as defined in
2 subsection (h)(2)) is equal to the sum of the following:

3 “(A) REINSURANCE BETWEEN INITIAL REINSUR-
4 ANCE THRESHOLD AND THE INITIAL COVERAGE
5 LIMIT.—For the portion of the individual’s gross cov-
6 ered prescription drug costs (as defined in paragraph
7 (3)) for the year that exceeds the initial reinsurance
8 threshold specified in paragraph (4), but does not ex-
9 ceed the initial coverage limit specified in section
10 1860D–2(b)(3), an amount equal to 20 percent of the
11 allowable costs (as defined in paragraph (2)) attrib-
12 utable to such gross covered prescription drug costs.

13 “(B) REINSURANCE ABOVE ANNUAL OUT-OF-
14 POCKET THRESHOLD.—For the portion of the individ-
15 ual’s gross covered prescription drug costs for the year
16 that exceeds the annual out-of-pocket threshold speci-
17 fied in 1860D–2(b)(4)(B), an amount equal to 80 per-
18 cent of the allowable costs attributable to such gross
19 covered prescription drug costs.

20 “(2) ALLOWABLE COSTS.—For purposes of this sec-
21 tion, the term ‘allowable costs’ means, with respect to gross
22 covered prescription drug costs under a plan described in
23 subsection (b) offered by a qualifying entity, the part of
24 such costs that are actually paid (net of discounts,
25 chargebacks, and average percentage rebates) under the
26 plan, but in no case more than the part of such costs that
27 would have been paid under the plan if the prescription
28 drug coverage under the plan were standard coverage.

29 “(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—
30 For purposes of this section, the term ‘gross covered pre-
31 scription drug costs’ means, with respect to an enrollee
32 with a qualifying entity under a plan described in sub-
33 section (b) during a coverage year, the costs incurred under
34 the plan (including costs attributable to administrative
35 costs) for covered prescription drugs dispensed during the
36 year, including costs relating to the deductible, whether
37 paid by the enrollee or under the plan, regardless of wheth-

1 er the coverage under the plan exceeds standard coverage
2 and regardless of when the payment for such drugs is
3 made.

4 “(4) INITIAL REINSURANCE THRESHOLD.—The initial
5 reinsurance threshold specified in this paragraph—

6 “(A) for 2006, is equal to \$1,000; or

7 “(B) for a subsequent year, is equal to the pay-
8 ment threshold specified in this paragraph for the pre-
9 vious year, increased by the annual percentage increase
10 described in section 1860D-2(b)(5) for the year in-
11 volved.

12 Any amount determined under subparagraph (B) that is
13 not a multiple of \$10 shall be rounded to the nearest mul-
14 tiple of \$10.

15 “(5) QUALIFYING COVERED INDIVIDUAL DEFINED.—
16 For purposes of this subsection, the term ‘qualifying cov-
17 ered individual’ means an individual who—

18 “(A) is enrolled with a prescription drug plan
19 under this part; or

20 “(B) is enrolled with a MA-EFFS Rx plan.

21 “(d) ADJUSTMENT OF PAYMENTS.—

22 “(1) ADJUSTMENT OF REINSURANCE PAYMENTS TO
23 ASSURE 30 PERCENT LEVEL OF SUBSIDY THROUGH REIN-
24 SURANCE.—

25 “(A) ESTIMATION OF PAYMENTS.—The Adminis-
26 trator shall estimate—

27 “(i) the total payments to be made (without
28 regard to this subsection) during a year under sub-
29 sections (a)(2) and (c); and

30 “(ii) the total payments to be made by quali-
31 fying entities for standard coverage under plans de-
32 scribed in subsection (b) during the year.

33 “(B) ADJUSTMENT.—The Administrator shall pro-
34 portionally adjust the payments made under sub-
35 sections (a)(2) and (c) for a coverage year in such
36 manner so that the total of the payments made under
37 such subsections (and under subsection (f)(3) insofar

1 as such payments reflect payments that would have
2 been made under such subsections if such subsections
3 had applied to qualified retiree prescription drug plans
4 instead of subsections (a)(3) and (f)(3)) for the year is
5 equal to 30 percent of the total payments described in
6 subparagraph (A)(ii).

7 “(2) RISK ADJUSTMENT FOR DIRECT SUBSIDIES.—To
8 the extent the Administrator determines it appropriate to
9 avoid risk selection, the payments made for direct subsidies
10 under subsection (a)(1) are subject to adjustment based
11 upon risk factors specified by the Administrator. Any such
12 risk adjustment shall be designed in a manner as to not re-
13 sult in a change in the aggregate payments made under
14 such subsection.

15 “(e) PAYMENT METHODS.—

16 “(1) IN GENERAL.—Payments under this section shall
17 be based on such a method as the Administrator deter-
18 mines. The Administrator may establish a payment method
19 by which interim payments of amounts under this section
20 are made during a year based on the Administrator’s best
21 estimate of amounts that will be payable after obtaining all
22 of the information.

23 “(2) SOURCE OF PAYMENTS.—Payments under this
24 section shall be made from the Medicare Prescription Drug
25 Trust Fund.

26 “(f) RULES RELATING TO QUALIFIED RETIREE PRE-
27 SCRIPTON DRUG PLAN.—

28 “(1) DEFINITION.—For purposes of this section, the
29 term ‘qualified retiree prescription drug plan’ means em-
30 ployment-based retiree health coverage (as defined in para-
31 graph (4)(A)) if, with respect to an individual who is a par-
32 ticipant or beneficiary under such coverage and is eligible
33 to be enrolled in a prescription drug plan or a MA-EFFS
34 Rx plan under this part, the following requirements are
35 met:

36 “(A) ACTUARIAL EQUIVALENCE TO STANDARD
37 COVERAGE.—The Administrator determines (based on

1 an actuarial analysis by the Administrator) that cov-
2 erage provides at least the same actuarial value as
3 standard coverage. Such determination may be made
4 on an annual basis.

5 “(B) AUDITS.—The sponsor (and the plan) shall
6 maintain, and afford the Administrator access to, such
7 records as the Administrator may require for purposes
8 of audits and other oversight activities necessary to en-
9 sure the adequacy of prescription drug coverage and
10 the accuracy of payments made.

11 “(C) PROVISION OF CERTIFICATION OF PRESCRIP-
12 TION DRUG COVERAGE.—The sponsor of the plan shall
13 provide for issuance of certifications of the type de-
14 scribed in section 1860D–1(c)(2)(D).

15 “(2) LIMITATION ON BENEFIT ELIGIBILITY.—No pay-
16 ment shall be provided under this section with respect to
17 a participant or beneficiary in a qualified retiree prescrip-
18 tion drug plan unless the individual is—

19 “(A) is covered under the plan; and

20 “(B) is eligible to obtain qualified prescription
21 drug coverage under section 1860D–1 but did not elect
22 such coverage under this part (either through a pre-
23 scription drug plan or through a MA-EFFS Rx plan).

24 “(3) EMPLOYER AND UNION SPECIAL SUBSIDY
25 AMOUNTS.—

26 “(A) IN GENERAL.—For purposes of subsection
27 (a), the special subsidy payment amount under this
28 paragraph for a qualifying covered retiree(as defined in
29 paragraph (6)) for a coverage year (as defined in sub-
30 section (h)) enrolled in a qualifying entity described in
31 subsection (b)(3) under a qualified retiree prescription
32 drug plan is, for the portion of the individual’s gross
33 covered prescription drug costs for the year that ex-
34 ceeds the deductible amount specified in subparagraph
35 (B), an amount equal to, subject to subparagraph (D),
36 28 percent of the allowable costs attributable to such
37 gross covered prescription drug costs, but not to ex-

ceed, subject to subparagraph (C), \$5,000 (for plan years that end in 2006) in the case of any such individual for the year.

“(B) DEDUCTIBLE APPLICABLE.—Subject to subparagraph (C), the deductible under this subparagraph is equal to \$250 for plan years that end in 2006.

“(C) INDEXING.—The amount specified in subparagraph (A) and the amount of the deductible under subparagraph (B) for a year after 2006 shall be adjusted in the same manner as the annual deductible under section 1860D-2(b)(1) is annually adjusted under such section.

“(D) ADJUSTMENT CONTINGENCY.—The Secretary may adjust the percentage specified in subparagraph (A) with respect to plan years that end in a year in a manner so that the aggregate expenditures in the year under this section are the same as the aggregate expenditures that would have been made under this section (taking into account the effect of any adjustment under subsection (d)(1)(B)) if paragraphs (1) and (2) of subsection (a) had applied to qualified prescription drug coverage instead of this paragraph and subsection (a)(3).

“(4) RELATED DEFINITIONS.—As used in this section:

“(A) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term ‘employment-based retiree health coverage’ means health insurance or other coverage of health care costs for individuals eligible to enroll in a prescription drug plan or MA-EFFS Rx plan under this part (or for such individuals and their spouses and dependents) under a group health plan (including such a plan that is established or maintained under or pursuant to one or more collective bargaining agreements) based on their status as retired participants in such plan.

“(B) QUALIFYING COVERED RETIREE.—The term ‘qualifying covered retiree’ means an individual who is

1 eligible to obtain qualified prescription drug coverage
2 under section 1860D-1 but did not elect such coverage
3 under this part (either through a prescription drug
4 plan or through a MA-EFFS Rx plan) but is covered
5 under a qualified retiree prescription drug plan.

6 “(C) SPONSOR.—The term ‘sponsor’ means a plan
7 sponsor, as defined in section 3(16)(B) of the Em-
8 ployee Retirement Income Security Act of 1974.

9 “(5) CONSTRUCTION.—Nothing in this subsection
10 shall be construed as—

11 “(A) precluding an individual who is covered
12 under employment-based retiree health coverage from
13 enrolling in a prescription drug plan or in a MA-EFFS
14 plan;

15 “(B) precluding such employment-based retiree
16 health coverage or an employer or other person from
17 paying all or any portion of any premium required for
18 coverage under such a prescription drug plan or MA-
19 EFFS plan on behalf of such an individual; or

20 “(C) preventing such employment-based retiree
21 health coverage from providing coverage for retirees—

22 “(i) who are covered under a qualified retiree
23 prescription plan that is better than standard cov-
24 erage; or

25 “(ii) who are not covered under a qualified re-
26 tiree prescription plan but who are enrolled in a
27 prescription drug plan or a MA-EFFS Rx plan,
28 that is supplemental to the benefits provided under
29 such prescription drug plan or MA-EFFS Rx plan,
30 except that any such supplemental coverage (not
31 including payment of any premium referred to in
32 subparagraph (B)) shall be treated as primary cov-
33 erage to which section 1862(b)(2)(A)(i) is deemed
34 to apply.

35 “(g) COMPUTATION OF NATIONAL AVERAGE MONTHLY
36 BID AMOUNT.—

1 “(1) IN GENERAL.—For each year (beginning with
2 2006) the Administrator shall compute a national average
3 monthly bid amount equal to the average of the benchmark
4 bid amounts for each prescription drug plan and for each
5 MA-EFFS Rx plan (as computed under paragraph (2), but
6 excluding plans described in section 1851(a)(2)(C))) ad-
7 justed under paragraph (4) to take into account reinsur-
8 ance payments.

9 “(2) BENCHMARK BID AMOUNT DEFINED.—For pur-
10 poses of this subsection, the term ‘benchmark bid amount’
11 means, with respect to qualified prescription drug coverage
12 offered under—

13 “(A) a prescription drug plan that—

14 “(i) provides standard coverage (or alternative
15 prescription drug coverage the actuarial value is
16 equivalent to that of standard coverage), the PDP
17 bid; or

18 “(ii) provides alternative prescription drug
19 coverage the actuarial value of which is greater
20 than that of standard coverage, the PDP bid multi-
21 plied by the ratio of (I) the actuarial value of
22 standard coverage, to (II) the actuarial value of the
23 alternative coverage; or

24 “(B) a MA-EFFS Rx plan, the portion of the bid
25 amount that is attributable to statutory drug benefits
26 (described in section 1853(a)(1)(A)(ii)(II)).

27 For purposes of subparagraph (A), the term ‘PDP bid’
28 means, with respect to a prescription drug plan, the bid
29 amount for enrollment under the plan under this part (de-
30 termined without regard to any low-income subsidy under
31 section 1860D–7 or any late enrollment penalty under sec-
32 tion 1860D–1(c)(2)(B)).

33 “(3) WEIGHTED AVERAGE.—

34 “(A) IN GENERAL.—The monthly national average
35 monthly bid amount computed under paragraph (1)
36 shall be a weighted average, with the weight for each

1 plan being equal to the average number of beneficiaries
2 enrolled under such plan in the previous year.

3 “(B) SPECIAL RULE FOR 2006.—For purposes of
4 applying this subsection for 2006, the Administrator
5 shall establish procedures for determining the weighted
6 average under subparagraph (A) for 2005.

7 “(4) ADJUSTMENT TO ADD BACK IN VALUE OF REIN-
8 SURANCE SUBSIDIES.—The adjustment under this para-
9 graph, to take into account reinsurance payments under
10 subsection (c) making of 30 percent of total payments, is
11 such an adjustment as will make the national average
12 monthly bid amount represent represent 100 percent, in-
13 stead of representing 70 percent, of average payments
14 under this part.

15 “(h) COVERAGE YEAR DEFINED.—For purposes of this
16 section, the term ‘coverage year’ means a calendar year in
17 which covered outpatient drugs are dispensed if a claim for
18 payment is made under the plan for such drugs, regardless of
19 when the claim is paid.

20 **“SEC. 1860D-9. MEDICARE PRESCRIPTION DRUG TRUST**
21 **FUND.**

22 “(a) IN GENERAL.—There is created on the books of the
23 Treasury of the United States a trust fund to be known as the
24 ‘Medicare Prescription Drug Trust Fund’ (in this section re-
25 ferred to as the ‘Trust Fund’). The Trust Fund shall consist
26 of such gifts and bequests as may be made as provided in sec-
27 tion 201(i)(1), and such amounts as may be deposited in, or
28 appropriated to, such fund as provided in this part. Except as
29 otherwise provided in this section, the provisions of subsections
30 (b) through (i) of section 1841 shall apply to the Trust Fund
31 in the same manner as they apply to the Federal Supple-
32 mentary Medical Insurance Trust Fund under such section.

33 “(b) PAYMENTS FROM TRUST FUND.—

34 “(1) IN GENERAL.—The Managing Trustee shall pay
35 from time to time from the Trust Fund such amounts as
36 the Administrator certifies are necessary to make—

1 “(A) payments under section 1860D-7 (relating to
2 low-income subsidy payments);

3 “(B) payments under section 1860D-8 (relating
4 to subsidy payments); and

5 “(C) payments with respect to administrative ex-
6 penses under this part in accordance with section
7 201(g).

8 “(2) TRANSFERS TO MEDICAID ACCOUNT FOR IN-
9 CREASED ADMINISTRATIVE COSTS.—The Managing Trustee
10 shall transfer from time to time from the Trust Fund to
11 the Grants to States for Medicaid account amounts the Ad-
12 ministrator certifies are attributable to increases in pay-
13 ment resulting from the application of a higher Federal
14 matching percentage under section 1935(b).

15 “(c) DEPOSITS INTO TRUST FUND.—

16 “(1) LOW-INCOME TRANSFER.—There is hereby trans-
17 ferred to the Trust Fund, from amounts appropriated for
18 Grants to States for Medicaid, amounts equivalent to the
19 aggregate amount of the reductions in payments under sec-
20 tion 1903(a)(1) attributable to the application of section
21 1935(c).

22 “(2) APPROPRIATIONS TO COVER GOVERNMENT CON-
23 TRIBUTIONS.—There are authorized to be appropriated
24 from time to time, out of any moneys in the Treasury not
25 otherwise appropriated, to the Trust Fund, an amount
26 equivalent to the amount of payments made from the Trust
27 Fund under subsection (b), reduced by the amount trans-
28 ferred to the Trust Fund under paragraph (1).

29 “(d) RELATION TO SOLVENCY REQUIREMENTS.—Any pro-
30 vision of law that relates to the solvency of the Trust Fund
31 under this part shall take into account the Trust Fund and
32 amounts receivable by, or payable from, the Trust Fund.

33 **“SEC. 1860D-10. DEFINITIONS; APPLICATION TO MEDI-**
34 **CARE ADVANTAGE AND EFFS PROGRAMS;**
35 **TREATMENT OF REFERENCES TO PROVI-**
36 **SIONS IN PART C.**

37 “(a) DEFINITIONS.—For purposes of this part:

1 “(1) COVERED OUTPATIENT DRUGS.—The term ‘cov-
2 ered outpatient drugs’ is defined in section 1860D–2(f).

3 “(2) INITIAL COVERAGE LIMIT.—The term ‘initial cov-
4 erage limit’ means such limit as established under section
5 1860D–2(b)(3), or, in the case of coverage that is not
6 standard coverage, the comparable limit (if any) established
7 under the coverage.

8 “(3) MEDICARE PRESCRIPTION DRUG TRUST FUND.—
9 The term ‘Medicare Prescription Drug Trust Fund’ means
10 the Trust Fund created under section 1860D–9(a).

11 “(4) PDP SPONSOR.—The term ‘PDP sponsor’ means
12 an entity that is certified under this part as meeting the
13 requirements and standards of this part for such a sponsor.

14 “(5) PRESCRIPTION DRUG PLAN.—The term ‘prescrip-
15 tion drug plan’ means health benefits coverage that—

16 “(A) is offered under a policy, contract, or plan by
17 a PDP sponsor pursuant to, and in accordance with, a
18 contract between the Administrator and the sponsor
19 under section 1860D–4(b);

20 “(B) provides qualified prescription drug coverage;
21 and

22 “(C) meets the applicable requirements of the sec-
23 tion 1860D–3 for a prescription drug plan.

24 “(6) QUALIFIED PRESCRIPTION DRUG COVERAGE.—
25 The term ‘qualified prescription drug coverage’ is defined
26 in section 1860D–2(a).

27 “(7) STANDARD COVERAGE.—The term ‘standard cov-
28 erage’ is defined in section 1860D–2(b).

29 “(b) OFFER OF QUALIFIED PRESCRIPTION DRUG COV-
30 ERAGE UNDER MEDICARE ADVANTAGE AND EFFS PRO-
31 GRAMS.—

32 “(1) AS PART OF MEDICARE ADVANTAGE PLAN.—
33 Medicare Advantage organizations are required to offer
34 Medicare Advantage plans that include qualified prescrip-
35 tion drug coverage under part C pursuant to section
36 1851(j).

1 “(2) AS PART OF EFFS PLAN.—EFFS organizations
2 are required to offer EFFS plans that include qualified
3 prescription drug coverage under part E pursuant to sec-
4 tion 1860E-1(j).

5 “(c) APPLICATION OF PART C PROVISIONS UNDER THIS
6 PART.—For purposes of applying provisions of part C under
7 this part with respect to a prescription drug plan and a PDP
8 sponsor, unless otherwise provided in this part such provisions
9 shall be applied as if—

10 “(1) any reference to a Medicare Advantage or other
11 plan included a reference to a prescription drug plan;

12 “(2) any reference to a provider-sponsored organiza-
13 tion included a reference to a PDP sponsor;

14 “(3) any reference to a contract under section 1857
15 included a reference to a contract under section 1860D-
16 4(b); and

17 “(4) any reference to part C included a reference to
18 this part.

19 “(d) REPORT ON PHARMACY SERVICES PROVIDED TO
20 NURSING FACILITY PATIENTS.—

21 “(1) REVIEW.—Within 6 months after the date of the
22 enactment of this section, the Secretary shall review the
23 current standards of practice for pharmacy services pro-
24 vided to patients in nursing facilities.

25 “(2) EVALUATIONS AND RECOMMENDATIONS.—Spe-
26 cifically in the review under paragraph (1), the Secretary
27 shall—

28 “(A) assess the current standards of practice, clin-
29 ical services, and other service requirements generally
30 utilized for pharmacy services in the long-term care set-
31 ting;

32 “(B) evaluate the impact of those standards with
33 respect to patient safety, reduction of medication errors
34 and quality of care; and

35 “(C) recommend (in the Secretary’s report under
36 paragraph (3)) necessary actions and appropriate reim-
37 bursement to ensure the provision of prescription drugs

1 to medicare beneficiaries residing in nursing facilities
2 in a manner consistent with existing patient safety and
3 quality of care standards under applicable State and
4 Federal laws.

5 “(3) REPORT.—The Secretary shall submit a report to
6 the Congress on the Secretary’s findings and recommenda-
7 tions under this subsection, including a detailed description
8 of the Secretary’s plans to implement this part in a manner
9 consistent with applicable State and Federal laws designed
10 to protect the safety and quality of care of nursing facility
11 patients.”.

12 (b) ADDITIONAL CONFORMING CHANGES.—

13 (1) CONFORMING REFERENCES TO PREVIOUS PART
14 D.—Any reference in law (in effect before the date of the
15 enactment of this Act) to part D of title XVIII of the So-
16 cial Security Act is deemed a reference to part F of such
17 title (as in effect after such date).

18 (2) CONFORMING AMENDMENT PERMITTING WAIVER
19 OF COST-SHARING.—Section 1128B(b)(3) (42 U.S.C.
20 1320a-7b(b)(3)) is amended—

21 (A) by striking “and” at the end of subparagraph
22 (E);

23 (B) by striking the period at the end of subpara-
24 graph (F) and inserting “; and”; and

25 (C) by adding at the end the following new sub-
26 paragraph:

27 “(G) the waiver or reduction of any cost-sharing im-
28 posed under part D of title XVIII.”.

29 (3) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not
30 later than 6 months after the date of the enactment of this
31 Act, the Secretary of Health and Human Services shall
32 submit to the appropriate committees of Congress a legisla-
33 tive proposal providing for such technical and conforming
34 amendments in the law as are required by the provisions
35 of this subtitle.

36 (c) STUDY ON TRANSITIONING PART B PRESCRIPTION
37 DRUG COVERAGE.—Not later than January 1, 2005, the Medi-

1 care Benefits Administrator shall submit a report to Congress
2 that makes recommendations regarding methods for providing
3 benefits under part D of title XVIII of the Social Security Act
4 for outpatient prescription drugs for which benefits are pro-
5 vided under part B of such title.

6 **SEC. 102. OFFERING OF QUALIFIED PRESCRIPTION**
7 **DRUG COVERAGE UNDER MEDICARE ADVAN-**
8 **TAGE AND ENHANCED FEE-FOR-SERVICE**
9 **(EFFS) PROGRAM.**

10 (a) MEDICARE ADVANTAGE.—Section 1851 (42 U.S.C.
11 1395w–21) is amended by adding at the end the following new
12 subsection:

13 “(j) AVAILABILITY OF PRESCRIPTION DRUG BENEFITS
14 AND SUBSIDIES.—

15 “(1) OFFERING OF QUALIFIED PRESCRIPTION DRUG
16 COVERAGE.—A Medicare Advantage organization on and
17 after January 1, 2006—

18 “(A) may not offer a Medicare Advantage plan de-
19 scribed in section 1851(a)(2)(A) in an area unless ei-
20 ther that plan (or another Medicare Advantage plan of-
21 fered by the organization in that area) includes quali-
22 fied prescription drug coverage; and

23 “(B) may not offer the prescription drug coverage
24 (other than that required under parts A and B) to an
25 enrollee under a Medicare Advantage plan, unless such
26 drug coverage is at least qualified prescription drug
27 coverage and unless the requirements of this subsection
28 with respect to such coverage are met.

29 “(2) REQUIREMENT FOR ELECTION OF PART D COV-
30 ERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COV-
31 ERAGE.—For purposes of this part, an individual who has
32 not elected qualified prescription drug coverage under sec-
33 tion 1860D–1(b) shall be treated as being ineligible to en-
34 roll in a Medicare Advantage plan under this part that of-
35 fers such coverage.

36 “(3) COMPLIANCE WITH CERTAIN ADDITIONAL BENE-
37 FICIARY PROTECTIONS FOR PRESCRIPTION DRUG COV-

1 ERAGE.—With respect to the offering of qualified prescrip-
2 tion drug coverage by a Medicare Advantage organization
3 under this part on and after January 1, 2006, the organi-
4 zation and plan shall meet the requirements of subsections
5 (a) through (d) of section 1860D–3 in the same manner as
6 they apply to a PDP sponsor and a prescription drug plan
7 under part D and shall submit to the Administrator the in-
8 formation described in section 1860D–6(a)(2). The Admin-
9 istrator shall waive such requirements to the extent the Ad-
10 ministrator determines that such requirements duplicate re-
11 quirements otherwise applicable to the organization or plan
12 under this part.

13 “(4) AVAILABILITY OF PREMIUM AND COST-SHARING
14 SUBSIDIES.—In the case of low-income individuals who are
15 enrolled in a Medicare Advantage plan that provides quali-
16 fied prescription drug coverage, premium and cost-sharing
17 subsidies are provided for such coverage under section
18 1860D–7.

19 “(5) AVAILABILITY OF DIRECT AND REINSURANCE
20 SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—Medicare
21 Advantage organizations are provided direct and reinsur-
22 ance subsidy payments for providing qualified prescription
23 drug coverage under this part under section 1860D–8.

24 “(6) CONSOLIDATION OF DRUG AND NON-DRUG PRE-
25 MIUMS.—In the case of a Medicare Advantage plan that in-
26 cludes qualified prescription drug coverage, with respect to
27 an enrollee in such plan there shall be a single premium
28 for both drug and non-drug coverage provided under the
29 plan.

30 “(7) TRANSITION IN INITIAL ENROLLMENT PERIOD.—
31 Notwithstanding any other provision of this part, the an-
32 nual, coordinated election period under subsection (e)(3)(B)
33 for 2006 shall be the 6-month period beginning with No-
34 vember 2005.

35 “(8) QUALIFIED PRESCRIPTION DRUG COVERAGE;
36 STANDARD COVERAGE.—For purposes of this part, the
37 terms ‘qualified prescription drug coverage’ and ‘standard

1 coverage' have the meanings given such terms in section
2 1860D-2.”.

3 (b) APPLICATION TO EFFS PLANS.—Subsection (d) of
4 section 1860E-2, as added by section 201(a), is amended to
5 read as follows:

6 “(d) AVAILABILITY OF PRESCRIPTION DRUG BENEFITS
7 AND SUBSIDIES.—

8 “(1) OFFERING OF QUALIFIED PRESCRIPTION DRUG
9 COVERAGE.—An EFFS organization—

10 “(A) may not offer an EFFS plan in an area un-
11 less either that plan (or another EFFS plan offered by
12 the organization in that area) includes qualified pre-
13 scription drug coverage; and

14 “(B) may not offer the prescription drug coverage
15 (other than that required under parts A and B) to an
16 enrollee under an EFFS plan, unless such drug cov-
17 erage is at least qualified prescription drug coverage
18 and unless the requirements of this subsection with re-
19 spect to such coverage are met.

20 “(2) REQUIREMENT FOR ELECTION OF PART D COV-
21 ERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COV-
22 ERAGE.—For purposes of this part, an individual who has
23 not elected qualified prescription drug coverage under sec-
24 tion 1860D-1(b) shall be treated as being ineligible to en-
25 roll in an EFFS plan under this part that offers such cov-
26 erage.

27 “(3) COMPLIANCE WITH CERTAIN ADDITIONAL BENE-
28 FICIARY PROTECTIONS FOR PRESCRIPTION DRUG COV-
29 ERAGE.—With respect to the offering of qualified prescrip-
30 tion drug coverage by an EFFS organization under this
31 part, the organization and plan shall meet the requirements
32 of subsections (a) through (d) of section 1860D-3 in the
33 same manner as they apply to a PDP sponsor and a pre-
34 scription drug plan under part D and shall submit to the
35 Administrator the information described in section 1860D-
36 6(a)(2). The Administrator shall waive such requirements
37 to the extent the Administrator determines that such re-

quirements duplicate requirements otherwise applicable to the organization or plan under this part.

“(4) AVAILABILITY OF PREMIUM AND COST-SHARING SUBSIDIES.—In the case of low-income individuals who are enrolled in an EFFS plan that provides qualified prescription drug coverage, premium and cost-sharing subsidies are provided for such coverage under section 1860D–7.

“(5) AVAILABILITY OF DIRECT AND REINSURANCE SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—EFFS organizations are provided direct and reinsurance subsidy payments for providing qualified prescription drug coverage under this part under section 1860D–8.

“(6) CONSOLIDATION OF DRUG AND NON-DRUG PREMIUMS.—In the case of an EFFS plan that includes qualified prescription drug coverage, with respect to an enrollee in such plan there shall be a single premium for both drug and non-drug coverage provided under the plan.

“(7) QUALIFIED PRESCRIPTION DRUG COVERAGE; STANDARD COVERAGE.—For purposes of this part, the terms ‘qualified prescription drug coverage’ and ‘standard coverage’ have the meanings given such terms in section 1860D–2.”.

(c) CONFORMING AMENDMENTS.—Section 1851 (42 U.S.C. 1395w–21) is amended—

(1) in subsection (a)(1)—

(A) by inserting “(other than qualified prescription drug benefits)” after “benefits”;

(B) by striking the period at the end of subparagraph (B) and inserting a comma; and

(C) by adding after and below subparagraph (B) the following:

“and may elect qualified prescription drug coverage in accordance with section 1860D–1.”; and

(2) in subsection (g)(1), by inserting “and section 1860D–1(c)(2)(B)” after “in this subsection”.

(d) EFFECTIVE DATE.—The amendments made by this section apply to coverage provided on or after January 1, 2006.

1 **SEC. 103. MEDICAID AMENDMENTS.**

2 (a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME
3 SUBSIDIES.—

4 (1) REQUIREMENT.—Section 1902(a) (42 U.S.C.
5 1396a(a)) is amended—

6 (A) by striking “and” at the end of paragraph
7 (64);

8 (B) by striking the period at the end of paragraph
9 (65) and inserting “; and”; and

10 (C) by inserting after paragraph (65) the following
11 new paragraph:

12 “(66) provide for making eligibility determinations
13 under section 1935(a).”.

14 (2) NEW SECTION.—Title XIX is further amended—

15 (A) by redesignating section 1935 as section 1936;
16 and

17 (B) by inserting after section 1934 the following
18 new section:

19 “SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION
20 DRUG BENEFIT

21 “SEC. 1935. (a) REQUIREMENT FOR MAKING ELIGIBILITY
22 DETERMINATIONS FOR LOW-INCOME SUBSIDIES.—As a condi-
23 tion of its State plan under this title under section 1902(a)(66)
24 and receipt of any Federal financial assistance under section
25 1903(a), a State shall—

26 “(1) make determinations of eligibility for premium
27 and cost-sharing subsidies under (and in accordance with)
28 section 1860D-7;

29 “(2) inform the Administrator of the Medicare Bene-
30 fits Administration of such determinations in cases in
31 which such eligibility is established; and

32 “(3) otherwise provide such Administrator with such
33 information as may be required to carry out part D of title
34 XVIII (including section 1860D-7).

35 “(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE
36 COSTS.—

1 “(1) IN GENERAL.—The amounts expended by a State
2 in carrying out subsection (a) are, subject to paragraph
3 (2), expenditures reimbursable under the appropriate para-
4 graph of section 1903(a); except that, notwithstanding any
5 other provision of such section, the applicable Federal
6 matching rates with respect to such expenditures under
7 such section shall be increased as follows (but in no case
8 shall the rate as so increased exceed 100 percent):

9 “(A) For expenditures attributable to costs in-
10 curred during 2005, the otherwise applicable Federal
11 matching rate shall be increased by $6\frac{2}{3}$ percent of the
12 percentage otherwise payable (but for this subsection)
13 by the State.

14 “(B)(i) For expenditures attributable to costs in-
15 curred during 2006 and each subsequent year through
16 2018, the otherwise applicable Federal matching rate
17 shall be increased by the applicable percent (as defined
18 in clause (ii)) of the percentage otherwise payable (but
19 for this subsection) by the State.

20 “(ii) For purposes of clause (i), the ‘applicable
21 percent’ for—

22 “(I) 2006 is $13\frac{1}{3}$ percent; or

23 “(II) a subsequent year is the applicable per-
24 cent under this clause for the previous year in-
25 creased by $6\frac{2}{3}$ percentage points.

26 “(C) For expenditures attributable to costs in-
27 curred after 2018, the otherwise applicable Federal
28 matching rate shall be increased to 100 percent.

29 “(2) COORDINATION.—The State shall provide the Ad-
30 ministrator with such information as may be necessary to
31 properly allocate administrative expenditures described in
32 paragraph (1) that may otherwise be made for similar eligi-
33 bility determinations.”.

34 (b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID RE-
35 SPONSIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES
36 FOR DUALY ELIGIBLE INDIVIDUALS.—

1 (1) IN GENERAL.—Section 1903(a)(1) (42 U.S.C.
2 1396b(a)(1)) is amended by inserting before the semicolon
3 the following: “, reduced by the amount computed under
4 section 1935(c)(1) for the State and the quarter”.

5 (2) AMOUNT DESCRIBED.—Section 1935, as inserted
6 by subsection (a)(2), is amended by adding at the end the
7 following new subsection:

8 “(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION
9 DRUG COSTS FOR DUALY-ELIGIBLE BENEFICIARIES.—

10 “(1) IN GENERAL.—For purposes of section
11 1903(a)(1), for a State that is one of the 50 States or the
12 District of Columbia for a calendar quarter in a year (be-
13 ginning with 2005) the amount computed under this sub-
14 section is equal to the product of the following:

15 “(A) MEDICARE SUBSIDIES.—The total amount of
16 payments made in the quarter under section 1860D-7
17 (relating to premium and cost-sharing prescription
18 drug subsidies for low-income medicare beneficiaries)
19 that are attributable to individuals who are residents of
20 the State and are entitled to benefits with respect to
21 prescribed drugs under the State plan under this title
22 (including such a plan operating under a waiver under
23 section 1115).

24 “(B) STATE MATCHING RATE.—A proportion com-
25 puted by subtracting from 100 percent the Federal
26 medical assistance percentage (as defined in section
27 1905(b)) applicable to the State and the quarter.

28 “(C) PHASE-OUT PROPORTION.—The phase-out
29 proportion (as defined in paragraph (2)) for the quar-
30 ter.

31 “(2) PHASE-OUT PROPORTION.—For purposes of para-
32 graph (1)(C), the ‘phase-out proportion’ for a calendar
33 quarter in—

34 “(A) 2006 is 93- $\frac{1}{3}$ percent;

35 “(B) a subsequent year before 2021, is the phase-
36 out proportion for calendar quarters in the previous
37 year decreased by 6- $\frac{2}{3}$ percentage points; or

1 “(C) a year after 2020 is 0 percent.”.

2 (c) MEDICAID PROVIDING WRAP-AROUND BENEFITS.—
3 Section 1935, as so inserted and amended, is further amended
4 by adding at the end the following new subsection:

5 “(d) ADDITIONAL PROVISIONS.—

6 “(1) MEDICAID AS SECONDARY PAYOR.—In the case of
7 an individual who is entitled to qualified prescription drug
8 coverage under a prescription drug plan under part D of
9 title XVIII (or under a MA-EFFS Rx plan under part C
10 or E of such title) and medical assistance for prescribed
11 drugs under this title, medical assistance shall continue to
12 be provided under this title for prescribed drugs to the ex-
13 tent payment is not made under the prescription drug plan
14 or MA-EFFS Rx plan selected by the individual.

15 “(2) CONDITION.—A State may require, as a condition
16 for the receipt of medical assistance under this title with
17 respect to prescription drug benefits for an individual eligi-
18 ble to obtain qualified prescription drug coverage described
19 in paragraph (1), that the individual elect qualified pre-
20 scription drug coverage under section 1860D-1.”.

21 (d) TREATMENT OF TERRITORIES.—

22 (1) IN GENERAL.—Section 1935, as so inserted and
23 amended, is further amended—

24 (A) in subsection (a) in the matter preceding para-
25 graph (1), by inserting “subject to subsection (e)” after
26 “section 1903(a)”;

27 (B) in subsection (c)(1), by inserting “subject to
28 subsection (e)” after “1903(a)(1)”; and

29 (C) by adding at the end the following new sub-
30 section:

31 “(e) TREATMENT OF TERRITORIES.—

32 “(1) IN GENERAL.—In the case of a State, other than
33 the 50 States and the District of Columbia—

34 “(A) the previous provisions of this section shall
35 not apply to residents of such State; and

36 “(B) if the State establishes a plan described in
37 paragraph (2) (for providing medical assistance with

1 respect to the provision of prescription drugs to medi-
2 care beneficiaries), the amount otherwise determined
3 under section 1108(f) (as increased under section
4 1108(g)) for the State shall be increased by the
5 amount specified in paragraph (3).

6 “(2) PLAN.—The plan described in this paragraph is
7 a plan that—

8 “(A) provides medical assistance with respect to
9 the provision of covered outpatient drugs (as defined in
10 section 1860D–2(f)) to low-income medicare bene-
11 ficiaries; and

12 “(B) assures that additional amounts received by
13 the State that are attributable to the operation of this
14 subsection are used only for such assistance.

15 “(3) INCREASED AMOUNT.—

16 “(A) IN GENERAL.—The amount specified in this
17 paragraph for a State for a year is equal to the product
18 of—

19 “(i) the aggregate amount specified in sub-
20 paragraph (B); and

21 “(ii) the amount specified in section
22 1108(g)(1) for that State, divided by the sum of
23 the amounts specified in such section for all such
24 States.

25 “(B) AGGREGATE AMOUNT.—The aggregate
26 amount specified in this subparagraph for—

27 “(i) 2006, is equal to \$25,000,000; or

28 “(ii) a subsequent year, is equal to the aggre-
29 gate amount specified in this subparagraph for the
30 previous year increased by annual percentage in-
31 crease specified in section 1860D–2(b)(5) for the
32 year involved.

33 “(4) REPORT.—The Administrator shall submit to
34 Congress a report on the application of this subsection and
35 may include in the report such recommendations as the Ad-
36 ministrator deems appropriate.”.

1 (2) CONFORMING AMENDMENT.—Section 1108(f) (42
2 U.S.C. 1308(f)) is amended by inserting “and section
3 1935(e)(1)(B)” after “Subject to subsection (g)”.

4 (e) AMENDMENT TO BEST PRICE.—Section
5 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

6 (1) by striking “and” at the end of subclause (III);

7 (2) by striking the period at the end of subclause (IV)
8 and inserting “; and”; and

9 (3) by adding at the end the following new subclause:

10 “(V) any prices charged which are nego-
11 tiated by a prescription drug plan under part
12 D of title XVIII, by a MA-EFFS Rx plan
13 under part C or E of such title with respect to
14 covered outpatient drugs, or by a qualified re-
15 tiree prescription drug plan (as defined in sec-
16 tion 1860D–8(f)(1)) with respect to such drugs
17 on behalf of individuals entitled to benefits
18 under part A or enrolled under part B of such
19 title.”.

20 **SEC. 104. MEDIGAP TRANSITION.**

21 (a) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is
22 amended by adding at the end the following new subsection:

23 “(v) COVERAGE OF PRESCRIPTION DRUGS.—

24 “(1) IN GENERAL.—Notwithstanding any other provi-
25 sion of law, except as provided in paragraph (3) no new
26 medicare supplemental policy that provides coverage of ex-
27 penses for prescription drugs may be issued under this sec-
28 tion on or after January 1, 2006, to an individual unless
29 it replaces a medicare supplemental policy that was issued
30 to that individual and that provided some coverage of ex-
31 penses for prescription drugs. Nothing in this subsection
32 shall be construed as preventing the policy holder of a
33 medicare supplemental policy issued before January 1,
34 2006, from continuing to receive benefits under such policy
35 on and after such date.

36 “(2) ISSUANCE OF SUBSTITUTE POLICIES FOR BENE-
37 FICIARIES ENROLLED WITH A PLAN UNDER PART D.—

1 “(A) IN GENERAL.—The issuer of a medicare sup-
2 plemental policy—

3 “(i) may not deny or condition the issuance or
4 effectiveness of a medicare supplemental policy that
5 has a benefit package classified as ‘A’, ‘B’, ‘C’, ‘D’,
6 ‘E’, ‘F’, or ‘G’ (under the standards established
7 under subsection (p)(2)) and that is offered and is
8 available for issuance to new enrollees by such
9 issuer;

10 “(ii) may not discriminate in the pricing of
11 such policy, because of health status, claims experi-
12 ence, receipt of health care, or medical condition;
13 and

14 “(iii) may not impose an exclusion of benefits
15 based on a pre-existing condition under such policy,
16 in the case of an individual described in subparagraph
17 (B) who seeks to enroll under the policy not later than
18 63 days after the date of the termination of enrollment
19 described in such paragraph and who submits evidence
20 of the date of termination or disenrollment along with
21 the application for such medicare supplemental policy.

22 “(B) INDIVIDUAL COVERED.—An individual de-
23 scribed in this subparagraph is an individual who—

24 “(i) enrolls in a prescription drug plan under
25 part D; and

26 “(ii) at the time of such enrollment was en-
27 rolled and terminates enrollment in a medicare sup-
28 plemental policy which has a benefit package classi-
29 fied as ‘H’, ‘I’, or ‘J’ under the standards referred
30 to in subparagraph (A)(i) or terminates enrollment
31 in a policy to which such standards do not apply
32 but which provides benefits for prescription drugs.

33 “(C) ENFORCEMENT.—The provisions of para-
34 graph (4) of subsection (s) shall apply with respect to
35 the requirements of this paragraph in the same manner
36 as they apply to the requirements of such subsection.

1 “(3) NEW STANDARDS.—In applying subsection
2 (p)(1)(E) (including permitting the NAIC to revise its
3 model regulations in response to changes in law) with re-
4 spect to the change in benefits resulting from title I of the
5 Medicare Prescription Drug and Modernization Act of
6 2003, with respect to policies issued to individuals who are
7 enrolled in a plan under part D, the changes in standards
8 shall only provide for substituting (for the benefit packages
9 described in paragraph (2)(B)(ii) that included coverage for
10 prescription drugs) two benefit packages that may provide
11 for coverage of cost-sharing (other than the prescription
12 drug deductible) with respect to qualified prescription drug
13 coverage under such part. The two benefit packages shall
14 be consistent with the following:

15 “(A) FIRST NEW POLICY.—The policy described in
16 this subparagraph has the following benefits, notwith-
17 standing any other provision of this section relating to
18 a core benefit package:

19 “(i) Coverage of 50 percent of the cost-sharing
20 otherwise applicable, except coverage of 100 per-
21 cent of any cost-sharing otherwise applicable for
22 preventive benefits.

23 “(ii) No coverage of the part B deductible.

24 “(iii) Coverage for all hospital coinsurance for
25 long stays (as in the current core benefit package).

26 “(iv) A limitation on annual out-of-pocket ex-
27 penditures to \$4,000 in 2005 (or, in a subsequent
28 year, to such limitation for the previous year in-
29 creased by an appropriate inflation adjustment
30 specified by the Secretary).

31 “(B) SECOND NEW POLICY.—The policy described
32 in this subparagraph has the same benefits as the pol-
33 icy described in subparagraph (A), except as follows:

34 “(i) Substitute ‘75 percent’ for ‘50 percent’ in
35 clause (i) of such subparagraph.

36 “(ii) Substitute ‘\$2,000’ for ‘\$4,000’ in clause
37 (iv) of such subparagraph.

1 “(4) CONSTRUCTION.—Any provision in this section or
2 in a medicare supplemental policy relating to guaranteed
3 renewability of coverage shall be deemed to have been met
4 through the offering of other coverage under this sub-
5 section.”.

6 (b) NAIC REPORT TO CONGRESS ON MEDIGAP MOD-
7 ERNIZATION.—The Secretary shall request the National Asso-
8 ciation of Insurance Commissioners to submit to Congress, not
9 later than 18 months after the date of the enactment of this
10 Act, a report that includes recommendations on the moderniza-
11 tion of coverage under the medigap program under section
12 1882 of the Social Security Act (42 U.S.C. 1395ss).

13 **SEC. 105. MEDICARE PRESCRIPTION DRUG DISCOUNT**
14 **CARD ENDORSEMENT PROGRAM; TRANSI-**
15 **TIONAL RX ASSISTANCE.**

16 (a) IN GENERAL.—Title XVIII is amended by inserting
17 after section 1806 the following new section:

18 “MEDICARE PRESCRIPTION DRUG DISCOUNT CARD
19 ENDORSEMENT AND TRANSITIONAL RX ASSISTANCE PROGRAM

20 “SEC. 1807. (a) ESTABLISHMENT OF PROGRAM.—

21 “(1) IN GENERAL.—The Secretary (or the Medicare
22 Benefits Administrator pursuant to section 1809(c)(3)(C))
23 shall establish a program with 2 components:

24 “(A) CARD ENDORSEMENT COMPONENT.—A com-
25 ponent (in this section referred to as the ‘card endorse-
26 ment component’) to endorse prescription drug dis-
27 count card programs (each such program referred to as
28 an ‘endorsed program’) that meet the requirements of
29 this section in order to provide access to prescription
30 drug discounts for medicare beneficiaries throughout
31 the United States.

32 “(B) TRANSITIONAL RX ASSISTANCE COMPO-
33 NENT.—A component (in this section referred to as the
34 ‘transitional Rx assistance component’) to provide as
35 part of such card programs for funding to assist Rx as-
36 sistance eligible low-income beneficiaries in purchasing

1 covered outpatient prescription drugs through such pro-
2 grams.

3 The Secretary shall make available to medicare bene-
4 ficiaries information regarding both components of the pro-
5 gram.

6 “(2) LIMITED PERIOD OF OPERATION.—

7 “(A) CARD ENDORSEMENT PROGRAM.—The card
8 endorsement component is intended to begin as soon as
9 possible, but in no case later than 90 days after the
10 date of the enactment of this section.

11 “(B) RX ASSISTANCE PROGRAM.—The Rx assist-
12 ance component shall be implemented so it operates
13 during 2004 and 2005. The Secretary shall implement
14 such component by July 1, 2004.

15 “(C) TRANSITION; TERMINATION.—The Secretary
16 shall provide for an appropriate transition and dis-
17 continuation of both components on and after January
18 1, 2006.

19 “(b) REQUIREMENTS FOR CARD ENDORSEMENT COMPO-
20 NENT.—Under the card endorsement component, the Secretary
21 may not endorse a prescription drug discount card program
22 under this section unless the program meets the following re-
23 quirements:

24 “(1) SAVINGS TO MEDICARE BENEFICIARIES.—The
25 program passes on to medicare beneficiaries who enroll in
26 the program discounts, rebates, and other price concessions
27 on prescription drugs, including discounts negotiated with
28 manufacturers.

29 “(2) PROHIBITION ON APPLICATION ONLY TO MAIL
30 ORDER.—The program applies to drugs that are available
31 other than solely through mail order.

32 “(3) BENEFICIARY SERVICES.—The program provides
33 pharmaceutical support services, such as education and
34 counseling, and services to prevent adverse drug inter-
35 actions.

36 “(4) INFORMATION.—The program makes available to
37 medicare beneficiaries through the Internet and otherwise

1 information, including information on enrollment fees,
2 prices charged to beneficiaries, and services offered under
3 the program, that the Secretary identifies as being nec-
4 essary to provide for informed choice by beneficiaries
5 among endorsed programs.

6 “(5) DEMONSTRATED EXPERIENCE.—The program is
7 operated directly, or through arrangements with an affili-
8 ated organization, by an entity that has demonstrated expe-
9 rience and expertise in operating such a program or a simi-
10 lar program and has the ability to administer (directly or
11 through subcontracts and using a point-of-service claims
12 processing methodology) the transitional Rx assistance
13 component for Rx assistance eligible individuals enrolling in
14 the program.

15 “(6) QUALITY ASSURANCE.—Such operating entity has
16 in place adequate procedures for assuring quality service
17 under the program.

18 “(7) OPERATION OF ASSISTANCE PROGRAM.—The en-
19 tity meets such requirements relating to solvency, compli-
20 ance with financial reporting requirements, audit compli-
21 ance, and contractual guarantees as the Secretary finds
22 necessary for the operating entity to implement the Rx as-
23 sistance program. Such entity shall provide a method for
24 notifying Rx assistance eligible individuals (in a form and
25 manner and periodicity specified by the Secretary) of the
26 balance of contributions remaining available for use to pur-
27 chase covered outpatient drugs and biologicals.

28 “(8) ENROLLMENT FEES.—The program may charge
29 an annual enrollment fee, but the amount of such annual
30 fee may not exceed \$30 for 2004 and 2005. A State may
31 pay some or all of the fee for individuals residing in the
32 State, and such payment shall be treated as a contribution
33 under subsection (d)(7).

34 “(9) CONFIDENTIALITY PROTECTIONS.—The program
35 implements policies and procedures to safeguard the use
36 and disclosure of program beneficiaries’ individually identi-
37 fiable health information in a manner consistent with the

1 Federal regulations (concerning the privacy of individually
2 identifiable health information) promulgated under section
3 264(c) of the Health Insurance Portability and Account-
4 ability Act of 1996. The entity offering the program shall
5 be treated as a covered entity for purposes of the provisions
6 of subpart E of part 164 of title 45, Code of Federal Regu-
7 lations, adopted pursuant to the authority of the Secretary
8 under section 264(c) of the Health Insurance Portability
9 and Accountability Act of 1996 (42 U.S. C. 1320d-2 note).

10 “(10) PERIODIC REPORTS TO SECRETARY.—The entity
11 operating the program shall submit to the Secretary peri-
12 odic reports on performance, utilization, finances, Rx as-
13 sistance expenditures, and such other matters as the Sec-
14 retary may specify.

15 “(11) ADDITIONAL BENEFICIARY PROTECTIONS.—The
16 program meets such additional requirements as the Sec-
17 retary identifies to protect and promote the interest of
18 medicare beneficiaries, including requirements that ensure
19 that beneficiaries are not charged more than the lower of
20 the negotiated retail price or the usual and customary
21 price.

22 The prices negotiated by a prescription drug discount card pro-
23 gram endorsed under this section shall (notwithstanding any
24 other provision of law) not be taken into account for the pur-
25 poses of establishing the best price under section
26 1927(c)(1)(C).

27 “(c) CARD ENDORSEMENT PROGRAM OPERATION.—The
28 Secretary shall operate the program under this section con-
29 sistent with the following:

30 “(1) PROMOTION OF INFORMED CHOICE.—In order to
31 promote informed choice among endorsed prescription drug
32 discount card programs, the Secretary shall provide for the
33 dissemination of information which compares the prices
34 and services of such programs in a manner coordinated
35 with the dissemination of educational information on Medi-
36 care Advantage plans under parts C.

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1 “(2) OVERSIGHT.—The Secretary shall provide appro-
2 priate oversight to ensure compliance of endorsed programs
3 with the requirements of this section, including verification
4 and disclosure (upon request) of the discounts and services
5 provided, the amount of dispensing fees recognized, and au-
6 dits under section 1860D-2(d)(3).

7 “(3) USE OF MEDICARE TOLL-FREE NUMBER.—The
8 Secretary shall provide through the 1-800-medicare toll free
9 telephone number for the receipt and response to inquiries
10 and complaints concerning the program and programs en-
11 dorsed under this section.

12 “(4) SANCTIONS FOR ABUSIVE PRACTICES.—The Sec-
13 retary may implement intermediate sanctions or may re-
14 voke the endorsement of a program in the case of a pro-
15 gram that the Secretary determines no longer meets the re-
16 quirements of this section or that has engaged in false or
17 misleading marketing practices.

18 “(5) ENROLLMENT PRACTICES.—A medicare bene-
19 ficiary may not be enrolled in more than one endorsed pro-
20 gram at any time. A medicare beneficiary may change the
21 endorsed program in which the beneficiary is enrolled, but
22 may not make such change until the beneficiary has been
23 enrolled in a program for a minimum period of time speci-
24 fied by the Secretary. An individual who seeks assistance
25 under the Rx assistance component, except in extraordinary
26 circumstances specified by the Secretary, not change the
27 endorsed program in which the individual is enrolled except
28 once a year and in a manner specified by the Secretary.

29 “(d) TRANSITIONAL RX ASSISTANCE COMPONENT.—

30 “(1) IN GENERAL.—Under the transitional Rx assist-
31 ance component of the program, the Secretary shall make
32 available to each endorsed program and on behalf of Rx as-
33 sistance eligible individuals enrolled in such program a con-
34 tribution amount that may be used, through a designated
35 account system and electronic debit cards, the purchase of
36 covered outpatient drugs through the endorsed program.

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1 “(2) ELIGIBILITY.—For purposes of this section, the
2 term ‘Rx assistance eligible individual’ means an individual
3 residing in one of the 50 States or the District of Columbia
4 who—

5 “(A) is entitled to benefits under part A or en-
6 rolled under part B;

7 “(B) is enrolled under a discount card program
8 endorsed under this section;

9 “(C) has income (as determined using a method-
10 ology established by the Secretary that shall, to the ex-
11 tent specified by the Secretary, be the same method-
12 ology used in determining eligibility of subsidy eligible
13 individuals for subsidies under section 1860D-7) that
14 is at or below 135 percent of the Federal poverty line
15 (as defined in section 1860D-7(a)(4)(C)(ii)); and

16 “(D) is not eligible for coverage of, or assistance
17 for, outpatient prescription drugs under any of the fol-
18 lowing:

19 “(i) A medicaid plan under title XIX (includ-
20 ing under any waiver approved under section
21 1115).

22 “(ii) A Medicare+ Choice or Medicare Advan-
23 tage plan under part C if such plan offers any pre-
24 scription drug coverage in addition to the coverage
25 required under such part.

26 “(iii) Enrollment under a group health plan or
27 health insurance coverage.

28 “(iv) Enrollment under a medicare supple-
29 mental insurance policy.

30 “(v) Chapter 55 of title 10, United States
31 Code (relating to medical and dental care for mem-
32 bers of the uniformed services).

33 “(vi) Chapter 17 of title 38, United States
34 Code (relating to Veterans’ medical care).

35 “(vii) Enrollment under a plan under chapter
36 89 of title 5, United States Code (relating to the
37 Federal employees’ health benefits program).

1 “(viii) The Indian Health Care Improvement
2 Act (25 U.S.C. 1601 et seq.).

3 An individual who has been determined to be a qualified
4 medicare beneficiary under section 1905(p) or eligible for
5 medical assistance under section 1902(a)(10)(E) is deemed
6 to meet the income requirements of subparagraph (C). Re-
7 ceipt of assistance for prescription drugs under a State
8 pharmaceutical assistance program shall not be treated as
9 coverage or assistance described in subparagraph (D).

10 “(3) INCOME DETERMINATIONS.—The provisions of
11 section 1860D–7(4)(C) shall apply for purposes of applying
12 this subsection.

13 “(4) FORM OF CONTRIBUTION.—The Secretary shall
14 specify the form and manner in which contributions are
15 made to endorsed programs on behalf of Rx assistance eli-
16 gible individuals enrolled in the programs consistent with
17 the following principles:

18 “(A) Contributions are pro-rated on a monthly or
19 similar basis and are computed (in the case of an indi-
20 vidual who becomes an Rx assistance eligible individual
21 during a year) for the number of months remaining in
22 the year.

23 “(B) Such contributions are not available for obli-
24 gation for covered outpatient drugs and biologicals dis-
25 pensed on or after January 1, 2006.

26 “(5) ANNUAL AMOUNT OF CONTRIBUTION.—The an-
27 nual amount of contribution to the account of an Rx assist-
28 ance eligible individual is \$500.

29 “(6) APPLICATION OF CONTRIBUTION.—With respect
30 to an Rx assistance eligible individual enrolled in an en-
31 dorsed program, the amount of the contribution may only
32 be used for the purchase of covered outpatient drugs and
33 biologicals using the discount card system available under
34 such program. The entity offering such program shall pro-
35 vide assurances satisfactory to the Secretary that access is
36 available (in a manner consistent with section 1860D–
37 3(c)(1)) to a range of participating pharmacies.

1 “(7) ADDITIONAL CONTRIBUTIONS AUTHORIZED.—The
2 Secretary may establish a process by which States, family
3 members, nonprofit organizations, employers, and other
4 persons may make contributions to the accounts sponsored
5 by endorsed programs on behalf of Rx assistance eligible
6 individuals, but in no case shall such a contribution be con-
7 sidered medical or child assistance for purposes of titles
8 XIX and XXI.

9 “(8) ROLLOVER.—Amounts contributed under this
10 subsection on behalf of, and into the account of, an Rx as-
11 sistance eligible individual at any time shall remain avail-
12 able for expenditure from such account with respect to cov-
13 ered outpatient drugs and biologicals furnished during the
14 period in which the program under this section operates.

15 “(9) REIMBURSEMENT FOR OPERATION OF COMPO-
16 NENT.—The Secretary shall, from the amounts appro-
17 priated under subsection (g), provide for payments to enti-
18 ties operating the program for the performance of activities
19 required under the transitional Rx assistance component.

20 “(e) USE OF STATE PHARMACEUTICAL ASSISTANCE PRO-
21 GRAMS.—The Secretary may enter into arrangements with
22 States in which State pharmaceutical assistance program in ef-
23 fect before June 1, 2003, shall be treated in the same manner
24 as an entity operating a transitional Rx assistance component
25 under this section and shall be eligible to receive and disburse
26 contributions in that same manner.

27 “(f) APPLICATION IN TERRITORIES.—

28 “(1) IN GENERAL.—Notwithstanding the previous pro-
29 visions of this section, of the amounts made available under
30 paragraph (3), the Secretary shall make available to States
31 (other than the 50 States and the District of Columbia) a
32 percentage (determined consistent with the allotment pro-
33 vided to territories under the State children’s health insur-
34 ance program under section 2104(c)) among the common-
35 wealths and territories described in section 2104(c)(3) in
36 the same proportion as the allotment proportion under such

1 program is allowed among such commonwealths and terri-
2 tories.

3 “(2) USE OF AMOUNTS.—Amounts made available
4 under this subsection may only be used by the State for the
5 provision of transitional Rx assistance in such manner as
6 the State may provide in a plan.

7 “(3) APPROPRIATION.—There are hereby appro-
8 priated, out of any money in the Treasury not otherwise
9 appropriated, an amount equal to \$1,500,000 for fiscal
10 year 2004 and \$2,500,000 for fiscal year 2005. Amounts
11 appropriated pursuant to this subsection for a fiscal year
12 shall remain available for expenditure through the end of
13 the year in which the fiscal year ends.

14 “(g) AUTHORIZATION OF APPROPRIATIONS.—There are
15 authorized to be appropriated such sums as may be necessary
16 to carry out this section.

17 “(h) INTERIM, FINAL REGULATORY AUTHORITY.—In
18 order to carry out this section in a timely manner, the Sec-
19 retary may promulgate regulations that take effect on an in-
20 terim basis, after notice and pending opportunity for public
21 comment.”.

22 (b) CONFORMING AMENDMENT.—Section
23 1927(c)(1)(C)(i)(V) (42 U.S.C. 1396r-8(c)(1)(C)(i)(V)), as
24 added by section 103(e), is amended by striking “or by a quali-
25 fied retiree prescription drug plan (as defined in section
26 1860D-8(f)(1))” and inserting “by a qualified retiree prescrip-
27 tion drug plan (as defined in section 1860D-8(f)(1)), or by a
28 prescription drug discount card program endorsed under sec-
29 tion 1807”.

30 **SEC. 106. DISCLOSURE OF RETURN INFORMATION FOR**
31 **PURPOSES OF CARRYING OUT MEDICARE**
32 **CATASTROPHIC PRESCRIPTION DRUG PRO-**
33 **GRAM.**

34 (a) IN GENERAL.—Subsection (l) of section 6103 of the
35 Internal Revenue Code of 1986 (relating to disclosure of re-
36 turns and return information for purposes other than tax ad-

1 ministration) is amended by adding at the end the following
2 new paragraph:

3 “(19) DISCLOSURE OF RETURN INFORMATION FOR
4 PURPOSES OF CARRYING OUT MEDICARE CATASTROPHIC
5 PRESCRIPTION DRUG PROGRAM.—

6 “(A) IN GENERAL.—The Secretary may, upon
7 written request from the Secretary of Health and
8 Human Services under section 1860D–2(b)(4)(E)(i) of
9 the Social Security Act, disclose to officers and employ-
10 ees of the Department of Health and Human Services
11 with respect to a specified taxpayer for the taxable year
12 specified by the Secretary of Health and Human Serv-
13 ices in such request—

14 “(i) the taxpayer identity information with re-
15 spect to such taxpayer, and

16 “(ii) the adjusted gross income of such tax-
17 payer for the taxable year (or, if less, the income
18 threshold limit specified in section 1860D–
19 2(b)(4)(D)(ii) for the calendar year specified by
20 such Secretary in such request).

21 “(B) SPECIFIED TAXPAYER.—For purposes of this
22 paragraph, the term ‘specified taxpayer’ means any
23 taxpayer who—

24 “(i) is identified by the Secretary of Health
25 and Human Services in the request referred to in
26 subparagraph (A), and

27 “(ii) either—

28 “(I) has an adjusted gross income for the
29 taxable year referred to in subparagraph (A) in
30 excess of the income threshold specified in sec-
31 tion 1860D–2(b)(4)(D)(ii) of such Act for the
32 calendar year referred to in such subparagraph,
33 or

34 “(II) is identified by such Secretary under
35 subparagraph (A) as being an individual who
36 elected to use more recent information under
37 section 1860D–2(b)(4)(D)(v) of such Act.

1 “(C) JOINT RETURNS.—In the case of a joint re-
2 turn, the Secretary shall, for purposes of applying this
3 paragraph, treat each spouse as a separate taxpayer
4 having an adjusted gross income equal to one-half of
5 the adjusted gross income determined with respect to
6 such return.

7 “(D) RESTRICTION ON USE OF DISCLOSED INFOR-
8 MATION.—Return information disclosed under subpara-
9 graph (A) may be used by officers and employees of the
10 Department of Health and Human Services only for
11 the purpose of administering the prescription drug ben-
12 efit under title XVIII of the Social Security Act. Such
13 officers and employees may disclose the annual out-of-
14 pocket threshold which applies to an individual under
15 such part to the entity that offers the plan referred to
16 in section 1860D–2(b)(4)(E)(ii) of such Act in which
17 such individual is enrolled. Such sponsor may use such
18 information only for purposes of administering such
19 benefit.”.

20 (b) CONFIDENTIALITY.—Paragraph (3) of section 6103(a)
21 of such Code is amended by striking “or (16)” and inserting
22 “(16), or (19)”.

23 (c) PROCEDURES AND RECORDKEEPING RELATED TO DIS-
24 CLOSURES.—Subsection (p)(4) of section 6103 of such Code is
25 amended by striking “any other person described in subsection
26 (l)(16) or (17)” each place it appears and inserting “any other
27 person described in subsection (l)(16), (17), or (19)”.

28 (d) UNAUTHORIZED DISCLOSURE.—Paragraph (2) of sec-
29 tion 7213(a) of such Code is amended by striking “or (16)”
30 and inserting “(16), or (19)”.

31 (e) UNAUTHORIZED INSPECTION.—Subparagraph (B) of
32 section 7213A(a)(1) of such Code is amended by inserting “or
33 (19)” after “subsection (l)(18)”.

34 **SEC. 107. STATE PHARMACEUTICAL ASSISTANCE TRAN-**
35 **SITION COMMISSION.**

36 (a) ESTABLISHMENT.—

1 (1) IN GENERAL.—There is established, as of the first
2 day of the third month beginning after the date of the en-
3 actment of this Act, a State Pharmaceutical Assistance
4 Transition Commission (in this section referred to as the
5 “Commission”) to develop a proposal for addressing the
6 unique transitional issues facing State pharmaceutical as-
7 sistance programs, and program participants, due to the
8 implementation of the medicare prescription drug program
9 under part D of title XVIII of the Social Security Act.

10 (2) DEFINITIONS.—For purposes of this section:

11 (A) STATE PHARMACEUTICAL ASSISTANCE PRO-
12 GRAM DEFINED.—The term “State pharmaceutical as-
13 sistance program” means a program (other than the
14 medicaid program) operated by a State (or under con-
15 tract with a State) that provides as of the date of the
16 enactment of this Act assistance to low-income medi-
17 care beneficiaries for the purchase of prescription
18 drugs.

19 (B) PROGRAM PARTICIPANT.—The term “program
20 participant” means a low-income medicare beneficiary
21 who is a participant in a State pharmaceutical assist-
22 ance program.

23 (b) COMPOSITION.—The Commission shall include the fol-
24 lowing:

25 (1) A representative of each governor of each State
26 that the Secretary identifies as operating on a statewide
27 basis a State pharmaceutical assistance program that pro-
28 vides for eligibility and benefits that are comparable or
29 more generous than the low-income assistance eligibility
30 and benefits offered under part D of title XVIII of the So-
31 cial Security Act.

32 (2) Representatives from other States that the Sec-
33 retary identifies have in operation other State pharma-
34 ceutical assistance programs, as appointed by the Sec-
35 retary.

36 (3) Representatives of organizations that have an in-
37 herent interest in program participants or the program

1 itself, as appointed by the Secretary but not to exceed the
2 number of representatives under paragraphs (1) and (2).

3 (4) Representatives of Medicare Advantage organiza-
4 tions and other private health insurance plans, as ap-
5 pointed by the Secretary.

6 (5) The Secretary (or the Secretary's designee) and
7 such other members as the Secretary may specify

8 The Secretary shall designate a member to serve as chair of
9 the Commission and the Commission shall meet at the call of
10 the chair.

11 (c) DEVELOPMENT OF PROPOSAL.—The Commission shall
12 develop the proposal described in subsection (a) in a manner
13 consistent with the following principles:

14 (1) Protection of the interests of program participants
15 in a manner that is the least disruptive to such participants
16 and that includes a single point of contact for enrollment
17 and processing of benefits.

18 (2) Protection of the financial and flexibility interests
19 of States so that States are not financially worse off as a
20 result of the enactment of this title.

21 (3) Principles of medicare modernization provided
22 under title II of this Act.

23 (d) REPORT.—By not later than January 1, 2005, the
24 Commission shall submit to the President and the Congress a
25 report that contains a detailed proposal (including specific leg-
26 islative or administrative recommendations, if any) and such
27 other recommendations as the Commission deems appropriate.

28 (e) SUPPORT.—The Secretary shall provide the Commis-
29 sion with the administrative support services necessary for the
30 Commission to carry out its responsibilities under this section.

31 (f) TERMINATION.—The Commission shall terminate 30
32 days after the date of submission of the report under sub-
33 section (d).

**TITLE II—MEDICARE ENHANCED
FEE-FOR-SERVICE AND MEDI-
CARE ADVANTAGE PROGRAMS;
MEDICARE COMPETITION**

**SEC. 200. MEDICARE MODERNIZATION AND REVITALIZA-
TION.**

This title provides for—

(1) establishment of the medicare enhanced fee-for-service (EFFS) program under which medicare beneficiaries are provided access to a range of enhanced fee-for-service (EFFS) plans that may use preferred provider networks to offer an enhanced range of benefits;

(2) establishment of a Medicare Advantage program that offers improved managed care plans with coordinated care; and

(3) competitive bidding, in the style of the Federal Employees Health Benefits program (FEHBP), among enhanced fee-for-service plans and Medicare Advantage plans in order to promote greater efficiency and responsiveness to medicare beneficiaries.

**Subtitle A—Medicare Enhanced Fee-
for-Service Program**

**SEC. 201. ESTABLISHMENT OF ENHANCED FEE-FOR-
SERVICE (EFFS) PROGRAM UNDER MEDI-
CARE.**

(a) IN GENERAL.—Title XVIII, as amended by section 101(a), is amended—

(1) by redesignating part E as part F; and

(2) by inserting after part D the following new part:

“PART E—ENHANCED FEE-FOR-SERVICE PROGRAM

“OFFERING OF ENHANCED FEE-FOR-SERVICE PLANS

THROUGHOUT THE UNITED STATES

“SEC. 1860E-1. (a) ESTABLISHMENT OF PROGRAM.—

“(1) IN GENERAL.—The Administrator shall establish under this part beginning January 1, 2006, an enhanced fee-for-service program under which enhanced fee-for-serv-

1 ice plans (as defined in subsection (b)) are offered to
2 EFFS-eligible individuals (as so defined) in EFFS regions
3 throughout the United States.

4 “(2) EFFS REGIONS.—For purposes of this part the
5 Administrator shall establish EFFS regions throughout the
6 United States by dividing the entire United States into at
7 least 10 such regions. Before establishing such regions, the
8 Administrator shall conduct a market survey and analysis,
9 including an examination of current insurance markets, to
10 determine how the regions should be established. The re-
11 gions shall be established in a manner to take into consid-
12 eration maximizing full access for all EFFS-eligible individ-
13 uals, especially those residing in rural areas.

14 “(b) DEFINITIONS.—For purposes of this part:

15 “(1) EFFS ORGANIZATION.—The ‘EFFS organiza-
16 tion’ means an entity that the Administrator certifies as
17 meeting the requirements and standards applicable to such
18 organization under this part.

19 “(2) ENHANCED FEE-FOR-SERVICE PLAN; EFFS
20 PLAN.—The terms ‘enhanced fee-for-service plan’ and
21 ‘EFFS plan’ mean health benefits coverage offered under
22 a policy, contract, or plan by an EFFS organization pursu-
23 ant to and in accordance with a contract pursuant to sec-
24 tion 1860E-4(c), but only if the plan provides either fee-
25 for-service coverage described in the following subpara-
26 graph (A) or preferred provider coverage described in the
27 following subparagraph (B):

28 “(A) FEE-FOR-SERVICE COVERAGE.—The plan—

29 “(i) reimburses hospitals, physicians, and
30 other providers at a rate determined by the plan on
31 a fee-for-service basis without placing the provider
32 at financial risk;

33 “(ii) does not vary such rates for such a pro-
34 vider based on utilization relating to such provider;
35 and

36 “(iii) does not restrict the selection of pro-
37 viders among those who are lawfully authorized to

1 provide the covered services and agree to accept the
2 terms and conditions of payment established by the
3 plan.

4 “(B) PREFERRED PROVIDER COVERAGE.—The
5 plan—

6 “(i) has a network of providers that have
7 agreed to a contractually specified reimbursement
8 for covered benefits with the organization offering
9 the plan; and

10 “(ii) provides for reimbursement for all cov-
11 ered benefits regardless of whether such benefits
12 are provided within such network of providers.

13 “(3) EFFS ELIGIBLE INDIVIDUAL.—The term ‘EFFS
14 eligible individual’ means an eligible individual described in
15 section 1851(a)(3).

16 “(4) EFFS REGION.—The term ‘EFFS region’ means
17 a region established under subsection (a)(2).

18 “(c) APPLICATION OF CERTAIN ELIGIBILITY, ENROLL-
19 MENT, ETC. REQUIREMENTS.—The provisions of section 1851
20 (other than subsection (h)(4)(A)) shall apply to EFFS plans
21 offered by an EFFS organization in an EFFS region, including
22 subsection (g) (relating to guaranteed issue and renewal).

23 “OFFERING OF ENHANCED FEE-FOR-SERVICE (EFFS) PLANS

24 “SEC. 1860E-2. (a) PLAN REQUIREMENTS.—No EFFS
25 plan may be offered under this part in an EFFS region unless
26 the requirements of this part are met with respect to the plan
27 and EFFS organization offering the plan.

28 “(b) AVAILABLE TO ALL EFFS BENEFICIARIES IN THE
29 ENTIRE REGION.—With respect to an EFFS plan offered in an
30 EFFS region—

31 “(1) IN GENERAL.—The plan must be offered to all
32 EFFS-eligible individuals residing in the region.

33 “(2) ASSURING ACCESS TO SERVICES.—The plan shall
34 comply with the requirements of section 1852(d)(4).

35 “(c) BENEFITS.—

36 “(1) IN GENERAL.—Each EFFS plan shall provide to
37 members enrolled in the plan under this part benefits,

1 through providers and other persons that meet the applica-
2 ble requirements of this title and part A of title XI—

3 “(A) for the items and services described in sec-
4 tion 1852(a)(1);

5 “(B) that are uniform for the plan for all EFFE
6 eligible individuals residing in the same EFFE region;

7 “(C) that include a single deductible applicable to
8 benefits under parts A and B and include a cata-
9 strophic limit on out-of-pocket expenditures for such
10 covered benefits; and

11 “(D) that include benefits for prescription drug
12 coverage for each enrollee who elects under part D to
13 be provided qualified prescription drug coverage
14 through the plan.

15 “(2) DISAPPROVAL AUTHORITY.—The Administrator
16 shall not approve a plan of an EFFE organization if the
17 Administrator determines (pursuant to the last sentence of
18 section 1852(b)(1)(A)) that the benefits are designed to
19 substantially discourage enrollment by certain EFFE eligi-
20 ble individuals with the organization.

21 “(d) OUTPATIENT PRESCRIPTION DRUG COVERAGE.—For
22 rules concerning the offering of prescription drug coverage
23 under EFFE plans, see the amendment made by section
24 102(b)(1) of the Medicare Prescription Drug and Moderniza-
25 tion Act of 2003.

26 “(e) OTHER ADDITIONAL PROVISIONS.—The provisions of
27 section 1852 (other than subsection (a)(1)) shall apply under
28 this part to EFFE plans. For the application of chronic care
29 improvement provisions, see the amendment made by section
30 722(b).

31 “SUBMISSION OF BIDS; BENEFICIARY SAVINGS; PAYMENT OF
32 PLANS

33 “SEC. 1860E-3. (a) SUBMISSION OF BIDS.—

34 “(1) REQUIREMENT.—

35 “(A) EFFE MONTHLY BID AMOUNT.—For each
36 year (beginning with 2006), an EFFE organization
37 shall submit to the Administrator an EFFE monthly

1 bid amount for each EFFE plan offered in each region.
2 Each such bid is referred to in this section as the
3 'EFFE monthly bid amount'.

4 "(B) FORM.—Such bid amounts shall be sub-
5 mitted for each such plan and region in a form and
6 manner and time specified by the Administrator, and
7 shall include information described in paragraph
8 (3)(A).

9 "(2) UNIFORM BID AMOUNTS.—Each EFFE monthly
10 bid amount submitted under paragraph (1) by an EFFE
11 organization under this part for an EFFE plan in an
12 EFFE region may not vary among EFFE eligible individ-
13 uals residing in the EFFE region involved.

14 "(3) SUBMISSION OF BID AMOUNT INFORMATION BY
15 EFFE ORGANIZATIONS.—

16 "(A) INFORMATION TO BE SUBMITTED.—The in-
17 formation described in this subparagraph is as follows:

18 "(i) The EFFE monthly bid amount for provi-
19 sion of all items and services under this part, which
20 amount shall be based on average costs for a typ-
21 ical enrollee residing in the region, and the actu-
22 arial basis for determining such amount.

23 "(ii) The proportions of such bid amount that
24 are attributable to—

25 "(I) the provision of statutory non-drug
26 benefits (such portion referred to in this part
27 as the 'unadjusted EFFE statutory non-drug
28 monthly bid amount');

29 "(II) the provision of statutory prescrip-
30 tion drug benefits; and

31 "(III) the provision of non-statutory bene-
32 fits;

33 and the actuarial basis for determining such pro-
34 portions.

35 "(iii) Such additional information as the Ad-
36 ministrator may require to verify the actuarial
37 bases described in clauses (i) and (ii).

1 “(B) STATUTORY BENEFITS DEFINED.—For pur-
2 poses of this part:

3 “(i) The term ‘statutory non-drug benefits’
4 means benefits under section 1852(a)(1).

5 “(ii) The term ‘statutory prescription drug
6 benefits’ means benefits under part D.

7 “(iii) The term ‘statutory benefits’ means stat-
8 utory prescription drug benefits and statutory non-
9 drug benefits.

10 “(C) ACCEPTANCE AND NEGOTIATION OF BID
11 AMOUNTS.—The Administrator has the authority to ne-
12 gotiate regarding monthly bid amounts submitted
13 under subparagraph (A) (and the proportion described
14 in subparagraph (A)(ii)), and for such purpose, the Ad-
15 ministrator has negotiation authority that the Director
16 of the Office of Personnel Management has with re-
17 spect to health benefits plans under chapter 89 of title
18 5, United States Code. The Administrator may reject
19 such a bid amount or proportion if the Administrator
20 determines that such amount or proportion is not sup-
21 ported by the actuarial bases provided under subpara-
22 graph (A).

23 “(D) CONTRACT AUTHORITY.—The Administrator
24 may, taking into account the unadjusted EFFS statu-
25 tory non-drug monthly bid amounts accepted under
26 subparagraph (C), enter into contracts for the offering
27 of up to 3 EFFS plans in any region.

28 “(b) PROVISION OF BENEFICIARY SAVINGS FOR CERTAIN
29 PLANS.—

30 “(1) BENEFICIARY REBATE RULE.—

31 “(A) REQUIREMENT.—The EFFS plan shall pro-
32 vide to the enrollee a monthly rebate equal to 75 per-
33 cent of the average per capita savings (if any) de-
34 scribed in paragraph (2) applicable to the plan and
35 year involved.

36 “(B) FORM OF REBATE.—A rebate required under
37 this paragraph shall be provided—

1 “(i) through the crediting of the amount of the
2 rebate towards the EFFS monthly prescription
3 drug beneficiary premium (as defined in section
4 1860E-4(a)(3)(B)) and the EFFS monthly supple-
5 mental beneficiary premium (as defined in section
6 1860E-4(a)(3)(C));

7 “(ii) through a direct monthly payment
8 (through electronic funds transfer or otherwise); or

9 “(iii) through other means approved by the
10 Medicare Benefits Administrator,

11 or any combination thereof.

12 “(2) COMPUTATION OF AVERAGE PER CAPITA MONTH-
13 LY SAVINGS.—For purposes of paragraph (1)(A), the aver-
14 age per capita monthly savings referred to in such para-
15 graph for an EFFS plan and year is computed as follows:

16 “(A) DETERMINATION OF REGION-WIDE AVERAGE
17 RISK ADJUSTMENT.—

18 “(i) IN GENERAL.—The Medicare Benefits Ad-
19 ministrator shall determine, at the same time rates
20 are promulgated under section 1853(b)(1) (begin-
21 ning with 2006), for each EFFS region the average
22 of the risk adjustment factors described in sub-
23 section (c)(3) to be applied to enrollees under this
24 part in that region. In the case of an EFFS region
25 in which an EFFS plan was offered in the previous
26 year, the Administrator may compute such average
27 based upon risk adjustment factors applied under
28 subsection (c)(3) in that region in a previous year.

29 “(ii) TREATMENT OF NEW REGIONS.—In the
30 case of a region in which no EFFS plan was of-
31 fered in the previous year, the Administrator shall
32 estimate such average. In making such estimate,
33 the Administrator may use average risk adjustment
34 factors applied to comparable EFFS regions or ap-
35 plied on a national basis.

1 “(B) DETERMINATION OF RISK ADJUSTED BENCH-
2 MARK AND RISK-ADJUSTED BID.—For each EFFS plan
3 offered in an EFFS region, the Administrator shall—

4 “(i) adjust the EFFS region-specific non-drug
5 monthly benchmark amount (as defined in para-
6 graph (3)) by the applicable average risk adjust-
7 ment factor computed under subparagraph (A);
8 and

9 “(ii) adjust the unadjusted EFFS statutory
10 non-drug monthly bid amount by such applicable
11 average risk adjustment factor.

12 “(C) DETERMINATION OF AVERAGE PER CAPITA
13 MONTHLY SAVINGS.—The average per capita monthly
14 savings described in this subparagraph is equal to the
15 amount (if any) by which—

16 “(i) the risk-adjusted benchmark amount com-
17 puted under subparagraph (B)(i), exceeds

18 “(ii) the risk-adjusted bid computed under
19 subparagraph (B)(ii).

20 “(3) COMPUTATION OF EFFS REGION-SPECIFIC NON-
21 DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of
22 this part, the term ‘EFFS region-specific non-drug monthly
23 benchmark amount’ means, with respect to an EFFS re-
24 gion for a month in a year, an amount equal to $\frac{1}{12}$ of the
25 average (weighted by number of EFFS eligible individuals
26 in each payment area described in section 1853(d)) of the
27 annual capitation rate as calculated under section
28 1853(c)(1) for that area.

29 “(c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

30 “(1) NON-DRUG BENEFITS.—Under a contract under
31 section 1860E-4(c) and subject to section 1853(g) (as
32 made applicable under subsection (d)), the Administrator
33 shall make monthly payments under this subsection in ad-
34 vance to each EFFS organization, with respect to coverage
35 of an individual under this part in an EFFS region for a
36 month, in an amount determined as follows:

1 “(A) PLANS WITH BIDS BELOW BENCHMARK.—In
2 the case of a plan for which there are average per cap-
3 ita monthly savings described in subsection (b)(2)(C),
4 the payment under this subsection is equal to the
5 unadjusted EFFS statutory non-drug monthly bid
6 amount, adjusted under paragraphs (3) and (4), plus
7 the amount of the monthly rebate computed under sub-
8 section (b)(1)(A) for that plan and year.

9 “(B) PLANS WITH BIDS AT OR ABOVE BENCH-
10 MARK.—In the case of a plan for which there are no
11 average per capita monthly savings described in sub-
12 section (b)(2)(C), the payment amount under this sub-
13 section is equal to the EFFS region-specific non-drug
14 monthly benchmark amount, adjusted under para-
15 graphs (3) and (4).

16 “(2) FOR FEDERAL DRUG SUBSIDIES.—In the case in
17 which an enrollee who elects under part D to be provided
18 qualified prescription drug coverage through the plan, the
19 EFFS organization offering such plan also is entitled—

20 “(A) to direct subsidy payment under section
21 1860D–8(a)(1);

22 “(B) to reinsurance subsidy payments under sec-
23 tion 1860D–8(a)(2); and

24 “(C) to reimbursement for premium and cost-shar-
25 ing reductions for low-income individuals under section
26 1860D–7(c)(3).

27 “(3) DEMOGRAPHIC RISK ADJUSTMENT, INCLUDING
28 ADJUSTMENT FOR HEALTH STATUS.—The Administrator
29 shall adjust under paragraph (1)(A) the unadjusted EFFS
30 statutory non-drug monthly bid amount and under para-
31 graph (1)(B) the EFFS region-specific non-drug monthly
32 benchmark amount for such risk factors as age, disability
33 status, gender, institutional status, and such other factors
34 as the Administrator determines to be appropriate, includ-
35 ing adjustment for health status under section 1853(a)(3)
36 (as applied under subsection (d)), so as to ensure actuarial
37 equivalence. The Administrator may add to, modify, or sub-

1 stitute for such adjustment factors if such changes will im-
2 prove the determination of actuarial equivalence.

3 “(4) ADJUSTMENT FOR INTRA-REGIONAL GEOGRAPHIC
4 VARIATIONS.—The Administrator shall also adjust such
5 amounts in a manner to take into account variations in
6 payments rates under part C among the different payment
7 areas under such part included in each EFFE region.

8 “(d) APPLICATION OF ADDITIONAL PAYMENT RULES.—
9 The provisions of section 1853 (other than subsections
10 (a)(1)(A), (d), and (e)) shall apply to an EFFE plan under this
11 part, except as otherwise provided in this section.

12 “PREMIUMS; ORGANIZATIONAL AND FINANCIAL REQUIREMENTS;
13 ESTABLISHMENT OF STANDARDS; CONTRACTS WITH EFFE
14 ORGANIZATIONS

15 “SEC. 1860E-4. (a) PREMIUMS.—

16 “(1) IN GENERAL.—The provisions of section 1854
17 (other than subsections (a)(6)(C) and (h)), including sub-
18 section (b)(5) relating to the consolidation of drug and non-
19 drug beneficiary premiums and subsection (c) relating to
20 uniform bids and premiums, shall apply to an EFFE plan
21 under this part, subject to paragraph (2).

22 “(2) CROSS-WALK.—In applying paragraph (1), any
23 reference in section 1854(b)(1)(A) or 1854(d) to—

24 “(A) a Medicare Advantage monthly basic bene-
25 ficiary premium is deemed a reference to the EFFE
26 monthly basic beneficiary premium (as defined in para-
27 graph (3)(A));

28 “(B) a Medicare Advantage monthly prescription
29 drug beneficiary premium is deemed a reference to the
30 EFFE monthly prescription drug beneficiary premium
31 (as defined in paragraph (3)(B)); and

32 “(C) a Medicare Advantage monthly supplemental
33 beneficiary premium is deemed a reference to the
34 EFFE monthly supplemental beneficiary premium (as
35 defined in paragraph (3)(C)).

36 “(3) DEFINITIONS.—For purposes of this part:

100

1 “(A) EFFS MONTHLY BASIC BENEFICIARY PRE-
2 MIUM.—The term ‘EFFS monthly basic beneficiary
3 premium’ means, with respect to an EFFS plan—

4 “(i) described in section 1860E–3(c)(1)(A)
5 (relating to plans providing rebates), zero; or

6 “(ii) described in section 1860E–3(c)(1)(B),
7 the amount (if any) by which the unadjusted
8 EFFS statutory non-drug monthly bid amount ex-
9 ceeds the EFFS region-specific non-drug monthly
10 benchmark amount (as defined in section 1860E–
11 3(b)(3)).

12 “(B) EFFS MONTHLY PRESCRIPTION DRUG BENE-
13 FICIARY PREMIUM.—The term ‘EFFS monthly pre-
14 scription drug beneficiary premium’ means, with re-
15 spect to an EFFS plan, the portion of the aggregate
16 monthly bid amount submitted under clause (i) of sec-
17 tion 1860E–3(a)(3)(A) for the year that is attributable
18 under such section to the provision of statutory pre-
19 scription drug benefits.

20 “(C) EFFS MONTHLY SUPPLEMENTAL BENE-
21 FICIARY PREMIUM.—The term ‘EFFS monthly supple-
22 mental beneficiary premium’ means, with respect to an
23 EFFS plan, the portion of the aggregate monthly bid
24 amount submitted under clause (i) of section 1860E–
25 3(a)(3)(A) for the year that is attributable under such
26 section to the provision of nonstatutory benefits.

27 “(b) ORGANIZATIONAL AND FINANCIAL REQUIRE-
28 MENTS.—The provisions of section 1855 shall apply to an
29 EFFS plan offered by an EFFS organization under this part.

30 “(c) CONTRACTS WITH EFFS ORGANIZATIONS.—The pro-
31 visions of section 1857 shall apply to an EFFS plan offered by
32 an EFFS organization under this part, except that any ref-
33 erence in such section to part C is deemed a reference to this
34 part.”.

35 (b) PROHIBITION ON COVERAGE UNDER MEDIGAP PLANS
36 OF DEDUCTIBLE IMPOSED UNDER EFFS PLANS.—Section

1 1882 (42 U.S.C. 1395ss), as amended by section 104(a), is
2 amended by adding at the end the following new subsection:

3 “(w) PROHIBITION ON COVERAGE OF DEDUCTIBLE AND
4 CERTAIN COST-SHARING IMPOSED UNDER EFFS PLANS.—
5 Notwithstanding any other provision of law, no medicare sup-
6 plemental policy (other than the 2 benefit packages described
7 in subsection (v)(3)) may provide for coverage of the single de-
8 ductible or more than 50 percent of other cost-sharing imposed
9 under an EFFS plan under part E.”.

10 (c) CONFORMING PROVISIONS.—Section 1882 of the Social
11 Security Act (42 U.S.C. 1395ss) shall be administered as if any
12 reference to a Medicare+ Choice organization offering a
13 Medicare+ Choice plan under part C of title XVIII of such Act
14 were a reference both to a Medicare Advantage organization of-
15 fering a Medicare Advantage plan under such part and an
16 EFFS organization offering an EFFS plan under part E of
17 such title.

18 **Subtitle B—Medicare Advantage** 19 **Program**

20 **CHAPTER 1—IMPLEMENTATION OF PROGRAM**

21 **SEC. 211. IMPLEMENTATION OF MEDICARE ADVANTAGE** 22 **PROGRAM.**

23 (a) IN GENERAL.—There is hereby established the Medi-
24 care Advantage program. The Medicare Advantage program
25 shall consist of the program under part C of title XVIII of the
26 Social Security Act, as amended by this title.

27 (b) REFERENCES.—Any reference to the program under
28 part C of title XVIII of the Social Security Act shall be deemed
29 a reference to the Medicare Advantage program and, with re-
30 spect to such part, any reference to “Medicare+ Choice” is
31 deemed a reference to “Medicare Advantage”.

32 **SEC. 212. MEDICARE ADVANTAGE IMPROVEMENTS.**

33 (a) EQUALIZING PAYMENTS WITH FEE-FOR-SERVICE.—

34 (1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C.
35 1395w-23(c)(1)) is amended by adding at the end the fol-
36 lowing:

1 “(D) BASED ON 100 PERCENT OF FEE-FOR-SERV-
2 ICE COSTS.—

3 “(i) IN GENERAL.—For 2004, the adjusted av-
4 erage per capita cost for the year involved, deter-
5 mined under section 1876(a)(4) for the Medicare
6 Advantage payment area for services covered under
7 parts A and B for individuals entitled to benefits
8 under part A and enrolled under part B who are
9 not enrolled in a Medicare Advantage under this
10 part for the year, but adjusted to exclude costs at-
11 tributable to payments under section 1886(h).

12 “(ii) INCLUSION OF COSTS OF VA AND DOD
13 MILITARY FACILITY SERVICES TO MEDICARE-ELIGI-
14 BLE BENEFICIARIES.—In determining the adjusted
15 average per capita cost under clause (i) for a year,
16 such cost shall be adjusted to include the Sec-
17 retary’s estimate, on a per capita basis, of the
18 amount of additional payments that would have
19 been made in the area involved under this title if
20 individuals entitled to benefits under this title had
21 not received services from facilities of the Depart-
22 ment of Veterans Affairs or the Department of De-
23 fense.”.

24 (2) CONFORMING AMENDMENT.—Such section is fur-
25 ther amended, in the matter before subparagraph (A), by
26 striking “or (C)” and inserting “(C), or (D)”.

27 (b) REVISION OF BLEND.—

28 (1) REVISION OF NATIONAL AVERAGE USED IN CAL-
29 CULATION OF BLEND.—Section 1853(c)(4)(B)(i)(II) (42
30 U.S.C. 1395w-23(c)(4)(B)(i)(II)) is amended by inserting
31 “who (with respect to determinations for 2004) are enrolled
32 in a Medicare+ Choice plan” after “the average number of
33 medicare beneficiaries”.

34 (2) CHANGE IN BUDGET NEUTRALITY.—Section
35 1853(c) (42 U.S.C. 1395w-23(c)) is amended—

36 (A) in paragraph (1)(A), by inserting “(for a year
37 before 2004)” after “multiplied”; and

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1 (B) in paragraph (5), by inserting “(before 2004)”
2 after “for each year”.

3 (c) INCREASING MINIMUM PERCENTAGE INCREASE TO
4 NATIONAL GROWTH RATE.—

5 (1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C.
6 1395w-23(c)(1)) is amended—

7 (A) in subparagraph (B)(iv), by striking “and
8 each succeeding year” and inserting “, 2003, and
9 2004”;

10 (B) in subparagraph (C)(iv), by striking “and each
11 succeeding year” and inserting “and 2003”; and

12 (C) by adding at the end of subparagraph (C) the
13 following new clause:

14 “(v) For 2004 and each succeeding year, the
15 greater of—

16 “(I) 102 percent of the annual Medicare
17 Advantage capitation rate under this paragraph
18 for the area for the previous year; or

19 “(II) the annual Medicare Advantage capi-
20 tation rate under this paragraph for the area
21 for the previous year increased by the national
22 per capita Medicare Advantage growth percent-
23 age, described in paragraph (6) for that suc-
24 ceeding year, but not taking into account for
25 any adjustment under paragraph (6)(C) for a
26 year before 2004.”.

27 (2) CONFORMING AMENDMENT.—Section
28 1853(c)(6)(C) (42 U.S.C. 1395w-23(c)(6)(C)) is amended
29 by inserting before the period at the end the following: “,
30 except that for purposes of paragraph (1)(C)(v)(II), no
31 such adjustment shall be made for a year before 2004”.

32 (d) INCLUSION OF COSTS OF DOD AND VA MILITARY FA-
33 CILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES IN
34 CALCULATION OF MEDICARE+ CHOICE PAYMENT RATES.—
35 Section 1853(c)(3) (42 U.S.C. 1395w-23(c)(3)) is amended—

36 (1) in subparagraph (A), by striking “subparagraph
37 (B)” and inserting “subparagraphs (B) and (E)”, and

1 (2) by adding at the end the following new subpara-
2 graph:

3 “(E) INCLUSION OF COSTS OF DOD AND VA MILI-
4 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE
5 BENEFICIARIES.—In determining the area-specific
6 Medicare+ Choice capitation rate under subparagraph
7 (A) for a year (beginning with 2004), the annual per
8 capita rate of payment for 1997 determined under sec-
9 tion 1876(a)(1)(C) shall be adjusted to include in the
10 rate the Secretary’s estimate, on a per capita basis, of
11 the amount of additional payments that would have
12 been made in the area involved under this title if indi-
13 viduals entitled to benefits under this title had not re-
14 ceived services from facilities of the Department of De-
15 fense or the Department of Veterans Affairs.”.

16 (e) EXTENDING SPECIAL RULE FOR CERTAIN INPATIENT
17 HOSPITAL STAYS TO REHABILITATION HOSPITALS.—

18 (1) IN GENERAL.—Section 1853(g) (42 U.S.C.
19 1395w-23(g)) is amended—

20 (A) by inserting “or from a rehabilitation facility
21 (as defined in section 1886(j)(1)(A))” after
22 “1886(d)(1)(B))”; and

23 (B) in paragraph (2)(B), by inserting “or section
24 1886(j), as the case may be,” after “1886(d)”.

25 (2) EFFECTIVE DATE.—The amendments made by
26 paragraph (1) shall apply to contract years beginning on or
27 after January 1, 2004.

28 (f) APPLICATION OF PRIVACY REGULATIONS.—Section
29 1852(h) (42 U.S.C. 1395w-22(h)) is amended by adding after
30 and below paragraph (3) the following:

31 “A Medicare Advantage organization shall be treated as a cov-
32 ered entity for purposes of the provisions of subpart E of part
33 164 of title 45, Code of Federal Regulations, adopted pursuant
34 to the authority of the Secretary under section 264(c) of the
35 Health Insurance Portability and Accountability Act of 1996
36 (42 U.S. C. 1320d-2 note).”.

37 (g) MEDPAC STUDY OF AAPCC.—

(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study that assesses the method used for determining the adjusted average per capita cost (AAPCC) under section 1876(a)(4) of the Social Security Act (42 U.S.C. 1395mm(a)(4)) as applied under section 1853(c)(1)(A) of such Act (as amended by subsection (a)). Such study shall include an examination of—

(A) the bases for variation in such costs between different areas, including differences in input prices, utilization, and practice patterns;

(B) the appropriate geographic area for payment under the Medicare Advantage program under part C of title XVIII of such Act; and

(C) the accuracy of risk adjustment methods in reflecting differences in costs of providing care to different groups of beneficiaries served under such program.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under paragraph (1).

(h) REPORT ON IMPACT OF INCREASED FINANCIAL ASSISTANCE TO MEDICARE ADVANTAGE PLANS.—Not later than July 1, 2006, the Medicare Benefits Administrator shall submit to Congress a report that describes the impact of additional financing provided under this Act and other Acts (including the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and BIPA) on the availability of Medicare Advantage plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

SEC. 221. COMPETITION PROGRAM BEGINNING IN 2006.

(a) SUBMISSION OF EFFS-LIKE BIDDING INFORMATION BEGINNING IN 2006.—Section 1854 (42 U.S.C. 1395w-24) is amended—

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1 (1) by amending the section heading to read as fol-
2 lows:

3 “PREMIUMS AND BID AMOUNT”;

4 (2) in subsection (a)(1)(A)—

5 (A) by striking “(A)” and inserting “(A)(i) if the
6 following year is before 2006,”; and

7 (B) by inserting before the semicolon at the end
8 the following: “or (ii) if the following year is 2006 or
9 later, the information described in paragraph (3) or
10 (6)(A) for the type of plan involved”; and

11 (3) by adding at the end of subsection (a) the fol-
12 lowing:

13 “(6) SUBMISSION OF BID AMOUNTS BY MEDICARE AD-
14 VANTAGE ORGANIZATIONS.—

15 “(A) INFORMATION TO BE SUBMITTED.—The in-
16 formation described in this subparagraph is as follows:

17 “(i) The monthly aggregate bid amount for
18 provision of all items and services under this part,
19 which amount shall be based on average costs for
20 a typical enrollee residing in the area, and the ac-
21 tual basis for determining such amount.

22 “(ii) The proportions of such bid amount that
23 are attributable to—

24 “(I) the provision of statutory non-drug
25 benefits (such portion referred to in this part
26 as the ‘unadjusted Medicare Advantage statu-
27 tory non-drug monthly bid amount’);

28 “(II) the provision of statutory prescrip-
29 tion drug benefits; and

30 “(III) the provision of non-statutory bene-
31 fits;

32 and the actuarial basis for determining such pro-
33 portions.

34 “(iii) Such additional information as the Ad-
35 ministrator may require to verify the actuarial
36 bases described in clauses (i) and (ii).

1 “(B) STATUTORY BENEFITS DEFINED.—For pur-
2 poses of this part:

3 “(i) The term ‘statutory non-drug benefits’
4 means benefits under section 1852(a)(1).

5 “(ii) The term ‘statutory prescription drug
6 benefits’ means benefits under part D.

7 “(iii) The term ‘statutory benefits’ means stat-
8 utory prescription drug benefits and statutory non-
9 drug benefits.

10 “(C) ACCEPTANCE AND NEGOTIATION OF BID
11 AMOUNTS.—

12 “(i) IN GENERAL.—Subject to clause (ii)—

13 “(I) the Administrator has the authority
14 to negotiate regarding monthly bid amounts
15 submitted under subparagraph (A) (and the
16 proportion described in subparagraph (A)(ii)),
17 and for such purpose and subject to such
18 clause, the Administrator has negotiation au-
19 thority that the Director of the Office of Per-
20 sonnel Management has with respect to health
21 benefits plans under chapter 89 of title 5,
22 United States Code; and

23 “(II) the Administrator may reject such a
24 bid amount or proportion if the Administrator
25 determines that such amount or proportion is
26 not supported by the actuarial bases provided
27 under subparagraph (A).

28 “(ii) EXCEPTION.—In the case of a plan de-
29 scribed in section 1851(a)(2)(C), the provisions of
30 clause (i) shall not apply and the provisions of
31 paragraph (5)(B), prohibiting the review, approval,
32 or disapproval of amounts described in such para-
33 graph, shall apply to the negotiation and rejection
34 of the monthly bid amounts and proportion re-
35 ferred to in subparagraph (A).”.

36 (b) PROVIDING FOR BENEFICIARY SAVINGS FOR CERTAIN
37 PLANS.—

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1 (1) IN GENERAL.—Section 1854(b) (42 U.S.C.
2 1395w-24(b)) is amended—

3 (A) by adding at the end of paragraph (1) the fol-
4 lowing new subparagraph:

5 “(C) BENEFICIARY REBATE RULE.—

6 “(i) REQUIREMENT.—The Medicare Advan-
7 tage plan shall provide to the enrollee a monthly re-
8 bate equal to 75 percent of the average per capita
9 savings (if any) described in paragraph (3) applica-
10 ble to the plan and year involved.

11 “(iii) FORM OF REBATE.—A rebate required
12 under this subparagraph shall be provided—

13 “(I) through the crediting of the amount
14 of the rebate towards the Medicare Advantage
15 monthly supplementary beneficiary premium or
16 the premium imposed for prescription drug cov-
17 erage under part D;

18 “(II) through a direct monthly payment
19 (through electronic funds transfer or other-
20 wise); or

21 “(III) through other means approved by
22 the Medicare Benefits Administrator,
23 or any combination thereof.”; and

24 (B) by adding at the end the following new para-
25 graphs:

26 “(3) COMPUTATION OF AVERAGE PER CAPITA MONTH-
27 LY SAVINGS.—For purposes of paragraph (1)(C)(i), the av-
28 erage per capita monthly savings referred to in such para-
29 graph for a Medicare Advantage plan and year is computed
30 as follows:

31 “(A) DETERMINATION OF STATE-WIDE AVERAGE
32 RISK ADJUSTMENT.—

33 “(i) IN GENERAL.—The Medicare Benefits Ad-
34 ministrator shall determine, at the same time rates
35 are promulgated under section 1853(b)(1) (begin-
36 ning with 2006), for each State the average of the
37 risk adjustment factors to be applied under section

1 1853(a)(1)(A) to payment for enrollees in that
2 State. In the case of a State in which a Medicare
3 Advantage plan was offered in the previous year,
4 the Administrator may compute such average based
5 upon risk adjustment factors applied in that State
6 in a previous year.

7 “(ii) TREATMENT OF NEW STATES.—In the
8 case of a State in which no Medicare Advantage
9 plan was offered in the previous year, the Adminis-
10 trator shall estimate such average. In making such
11 estimate, the Administrator may use average risk
12 adjustment factors applied to comparable States or
13 applied on a national basis.

14 “(B) DETERMINATION OF RISK ADJUSTED BENCH-
15 MARK AND RISK-ADJUSTED BID.—For each Medicare
16 Advantage plan offered in a State, the Administrator
17 shall—

18 “(i) adjust the Medicare Advantage area-spe-
19 cific non-drug monthly benchmark amount (as de-
20 fined in subsection (j)) by the applicable average
21 risk adjustment factor computed under subpara-
22 graph (A); and

23 “(ii) adjust the unadjusted Medicare Advan-
24 tage statutory non-drug monthly bid amount by
25 such applicable average risk adjustment factor.

26 “(C) DETERMINATION OF AVERAGE PER CAPITA
27 MONTHLY SAVINGS.—The average per capita monthly
28 savings described in this subparagraph is equal to the
29 amount (if any) by which—

30 “(i) the risk-adjusted benchmark amount com-
31 puted under subparagraph (B)(i), exceeds

32 “(ii) the risk-adjusted bid computed under
33 subparagraph (B)(ii).

34 “(D) AUTHORITY TO DETERMINE RISK ADJUST-
35 MENT FOR AREAS OTHER THAN STATES.—The Admin-
36 istrator may provide for the determination and applica-

tion of risk adjustment factors under this paragraph on the basis of areas other than States.

“(4) BENEFICIARY’S OPTION OF PAYMENT THROUGH WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, a Medicare Advantage organization shall permit each enrollee, at the enrollee’s option, to make payment of premiums under this part to the organization indirectly through withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839 or through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or otherwise.”.

(2) PROVISION OF SINGLE CONSOLIDATED PREMIUM.—Section 1854(b) (42 U.S.C. 1395w-24(b)), as amended by paragraph (1), is further amended by adding at the end the following new paragraph:

“(5) SINGLE CONSOLIDATED PREMIUM.—In the case of an enrollee in a Medicare Advantage plan who elects under part D to be provided qualified prescription drug coverage through the plan, the Administrator shall provide a mechanism for the consolidation of the beneficiary premium amount for non-drug benefits under this part with the premium amount for prescription drug coverage under part D provided through the plan.”.

(3) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG BENCHMARK.—Section 1853 (42 U.S.C. 1395w-23) is amended by adding at the end the following new subsection:

“(j) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term ‘Medicare Advantage area-specific non-drug monthly benchmark amount’ means, with respect to a Medicare Advantage payment area for a month in a year, an amount equal to $\frac{1}{12}$ of the annual Medicare Advantage capitation rate under section 1853(c)(1) for the area for the year.”.

1 (c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

2 (1) IN GENERAL.—Section 1853(a)(1)(A) (42 U.S.C.
3 1395w-23) is amended by striking “in an amount” and all
4 that follows and inserting the following: “in an amount de-
5 termined as follows:

6 “(i) PAYMENT BEFORE 2006.—For years be-
7 fore 2006, the payment amount shall be equal to
8 $\frac{1}{12}$ of the annual Medicare Advantage capitation
9 rate (as calculated under subsection (c)(1)) with re-
10 spect to that individual for that area, reduced by
11 the amount of any reduction elected under section
12 1854(f)(1)(E) and adjusted under clause (iv).

13 “(ii) PAYMENT FOR STATUTORY NON-DRUG
14 BENEFITS BEGINNING WITH 2006.—For years be-
15 ginning with 2006—

16 “(I) PLANS WITH BIDS BELOW BENCH-
17 MARK.—In the case of a plan for which there
18 are average per capita monthly savings de-
19 scribed in section 1854(b)(3)(C), the payment
20 under this subsection is equal to the
21 unadjusted Medicare Advantage statutory non-
22 drug monthly bid amount, adjusted under
23 clause (iv), plus the amount of the monthly re-
24 bate computed under section 1854(b)(1)(C)(i)
25 for that plan and year.

26 “(II) PLANS WITH BIDS AT OR ABOVE
27 BENCHMARK.—In the case of a plan for which
28 there are no average per capita monthly sav-
29 ings described in section 1854(b)(3)(C), the
30 payment amount under this subsection is equal
31 to the Medicare Advantage area-specific non-
32 drug monthly benchmark amount, adjusted
33 under clause (iv).

34 “(iii) FOR FEDERAL DRUG SUBSIDIES.—In the
35 case in which an enrollee who elects under part D
36 to be provided qualified prescription drug coverage

1 through the plan, the Medicare Advantage organi-
2 zation offering such plan also is entitled—

3 “(I) to direct subsidy payment under sec-
4 tion 1860D–8(a)(1);

5 “(II) to reinsurance subsidy payments
6 under section 1860D–8(a)(2); and

7 “(III) to reimbursement for premium and
8 cost-sharing reductions for low-income individ-
9 uals under section 1860D–7(c)(3).

10 “(iv) DEMOGRAPHIC ADJUSTMENT, INCLUDING
11 ADJUSTMENT FOR HEALTH STATUS.—The Admin-
12 istrator shall adjust the payment amount under
13 clause (i), the unadjusted Medicare Advantage stat-
14 utory non-drug monthly bid amount under clause
15 (ii)(I), and the Medicare Advantage area-specific
16 non-drug monthly benchmark amount under clause
17 (ii)(II) for such risk factors as age, disability sta-
18 tus, gender, institutional status, and such other
19 factors as the Administrator determines to be ap-
20 propriate, including adjustment for health status
21 under paragraph (3), so as to ensure actuarial
22 equivalence. The Administrator may add to, mod-
23 ify, or substitute for such adjustment factors if
24 such changes will improve the determination of ac-
25 tuarial equivalence.”.

26 (d) CONFORMING AMENDMENTS.—

27 (1) PROTECTION AGAINST BENEFICIARY SELECTION.—
28 Section 1852(b)(1)(A) (42 U.S.C. 1395w–22(b)(1)(A)) is
29 amended by adding at the end the following: “The Admin-
30 istrator shall not approve a plan of an organization if the
31 Administrator determines that the benefits are designed to
32 substantially discourage enrollment by certain Medicare
33 Advantage eligible individuals with the organization.”.

34 (2) CONFORMING AMENDMENT TO PREMIUM TERMI-
35 NOLOGY.—Section 1854(b)(2) (42 U.S.C. 1395w–24(b)(2))
36 is amended by redesignating subparagraph (C) as subpara-

graph (D) and by striking subparagraphs (A) and (B) and inserting the following:

“(A) MEDICARE ADVANTAGE MONTHLY BASIC BENEFICIARY PREMIUM.—The term ‘Medicare Advantage monthly basic beneficiary premium’ means, with respect to a Medicare Advantage plan—

“(i) described in section 1853(a)(1)(A)(ii)(I) (relating to plans providing rebates), zero; or

“(ii) described in section 1853(a)(1)(A)(ii)(II), the amount (if any) by which the unadjusted Medicare Advantage statutory non-drug monthly bid amount exceeds the Medicare Advantage area-specific non-drug monthly benchmark amount;

except that, in the case of a Medicare Advantage private fee-for-service plan, such term means such premium as the plan files with the Administrator under this section.

“(B) MEDICARE ADVANTAGE MONTHLY PRESCRIPTION DRUG BENEFICIARY PREMIUM.—The term ‘Medicare Advantage monthly prescription drug beneficiary premium’ means, with respect to a Medicare Advantage plan, that portion of the bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under such section to the provision of statutory prescription drug benefits.

“(C) MEDICARE ADVANTAGE MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The term ‘Medicare Advantage monthly supplemental beneficiary premium’ means, with respect to a Medicare Advantage plan, the portion of the aggregate monthly bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under such section to the provision of nonstatutory benefits.”.

(3) REQUIREMENT FOR UNIFORM PREMIUM AND BID AMOUNTS.—Section 1854(c) (42 U.S.C. 1395w–24(c)) is amended to read as follows:

1 “(c) UNIFORM PREMIUM AND BID AMOUNTS.—The Medi-
2 care Advantage monthly bid amount submitted under sub-
3 section (a)(6), the Medicare Advantage monthly basic, prescrip-
4 tion drug, and supplemental beneficiary premiums, and the
5 Medicare Advantage monthly MSA premium charged under
6 subsection (b) of a Medicare Advantage organization under this
7 part may not vary among individuals enrolled in the plan.”.

8 (4) PERMITTING BENEFICIARY REBATES.—

9 (A) Section 1851(h)(4)(A) (42 U.S.C. 1395w-
10 21(h)(4)(A)) is amended by inserting “except as pro-
11 vided under section 1854(b)(1)(C)” after “or other-
12 wise”.

13 (B) Section 1854(d) (42 U.S.C. 1395w-24(d)) is
14 amended by inserting “, except as provided under sub-
15 section (b)(1)(C),” after “and may not provide”.

16 (5) OTHER CONFORMING AMENDMENTS RELATING TO
17 BIDS.—Section 1854 (42 U.S.C. 1395w-24) is amended—

18 (A) in the heading of subsection (a), by inserting
19 “AND BID AMOUNTS” after “PREMIUMS”; and

20 (B) in subsection (a)(5)(A), by inserting “para-
21 graphs (2), (3), and (4) of” after “filed under”.

22 (e) ADDITIONAL CONFORMING AMENDMENTS.—

23 (1) ANNUAL DETERMINATION AND ANNOUNCEMENT
24 OF CERTAIN FACTORS.—Section 1853(b)(1) (42 U.S.C.
25 1395w-23(b)(1)) is amended by striking “the respective
26 calendar year” and all that follows and inserting the fol-
27 lowing: “the calendar year concerned with respect to each
28 Medicare Advantage payment area, the following:

29 “(A) PRE-COMPETITION INFORMATION.—For
30 years before 2006, the following:

31 “(i) MEDICARE ADVANTAGE CAPITATION
32 RATES.—The annual Medicare Advantage capita-
33 tion rate for each Medicare Advantage payment
34 area for the year.

35 “(ii) ADJUSTMENT FACTORS.—The risk and
36 other factors to be used in adjusting such rates

1 under subsection (a)(1)(A) for payments for
2 months in that year.

3 “(B) COMPETITION INFORMATION.—For years be-
4 ginning with 2006, the following:

5 “(i) BENCHMARK.—The Medicare Advantage
6 area-specific non-drug benchmark under section
7 1853(j).

8 “(ii) ADJUSTMENT FACTORS.—The adjust-
9 ment factors applied under section
10 1853(a)(1)(A)(iv) (relating to demographic adjust-
11 ment), section 1853(a)(1)(B) (relating to adjust-
12 ment for end-stage renal disease), and section
13 1853(a)(3) (relating to health status adjust-
14 ment).”.

15 (2) REPEAL OF PROVISIONS RELATING TO ADJUSTED
16 COMMUNITY RATE (ACR).—

17 (A) IN GENERAL.—Subsections (e) and (f) of sec-
18 tion 1854 (42 U.S.C. 1395w-24) are repealed.

19 (B) CONFORMING AMENDMENTS.—(i) Section
20 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by
21 striking “, and to reflect” and all that follows and in-
22 serting a period.

23 (ii) Section 1852(a)(1) (42 U.S.C. 1395w-
24 22(a)(1)) is amended by striking “title XI” and all that
25 follows and inserting the following: “title XI those
26 items and services (other than hospice care) for which
27 benefits are available under parts A and B to individ-
28 uals residing in the area served by the plan.”.

29 (iii) Section 1857(d)(1) (42 U.S.C. 1395w-
30 27(d)(1)) is amended by striking “, costs, and com-
31 putation of the adjusted community rate” and inserting
32 “and costs”.

33 (f) REFERENCES UNDER PART E.—Section 1859 (42
34 U.S.C. 1395w-29) is amended by adding at the end the fol-
35 lowing new subsection:

36 “(f) APPLICATION UNDER PART E.—In the case of any
37 reference under part E to a requirement or provision of this

1 part in the relation to an EFFE plan or organization under
2 such part, except as otherwise specified any such requirement
3 or provision shall be applied to such organization or plan in the
4 same manner as such requirement or provision applies to a
5 Medicare Advantage private fee-for-service plan (and the Medi-
6 care Advantage organization that offers such plan) under this
7 part.”.

8 (g) EFFECTIVE DATE.—The amendments made by this
9 section shall apply to payments and premiums for months be-
10 ginning with January 2006.

11 **CHAPTER 3—ADDITIONAL REFORMS**

12 **SEC. 231. MAKING PERMANENT CHANGE IN MEDICARE** 13 **ADVANTAGE REPORTING DEADLINES AND** 14 **ANNUAL, COORDINATED ELECTION PERIOD.**

15 (a) CHANGE IN REPORTING DEADLINE.—Section
16 1854(a)(1) (42 U.S.C. 1395w-24(a)(1)), as amended by sec-
17 tion 532(b)(1) of the Public Health Security and Bioterrorism
18 Preparedness and Response Act of 2002, is amended by strik-
19 ing “2002, 2003, and 2004 (or July 1 of each other year)” and
20 inserting “2002 and each subsequent year”.

21 (b) DELAY IN ANNUAL, COORDINATED ELECTION PE-
22 RIOD.—Section 1851(e)(3)(B) (42 U.S.C. 1395w-21(e)(3)(B)),
23 as amended by section 532(c)(1)(A) of the Public Health Secu-
24 rity and Bioterrorism Preparedness and Response Act of 2002,
25 is amended—

26 (1) by striking “and after 2005”; and

27 (2) by striking “, 2004, and 2005” and inserting “and
28 any subsequent year”.

29 (c) ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—Sec-
30 tion 1853(b)(1) (42 U.S.C. 1395w-23(b)(1)), as amended by
31 section 532(d)(1) of the Public Health Security and Bioter-
32 rorism Preparedness and Response Act of 2002, is amended—

33 (1) by striking “and after 2005”; and

34 (2) by striking “and 2005” and inserting “and each
35 subsequent year”.

36 (d) REQUIRING PROVISION OF AVAILABLE INFORMATION
37 COMPARING PLAN OPTIONS.—The first sentence of section

1 1851(d)(2)(A)(ii) (42 U.S.C. 1395w-21(d)(2)(A)(ii)) is amend-
2 ed by inserting before the period the following: “to the extent
3 such information is available at the time of preparation of ma-
4 terials for the mailing”.

5 **SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.**

6 (a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C. 1395w-
7 26(b)(3)) is amended to read as follows:

8 “(3) RELATION TO STATE LAWS.—The standards es-
9 tablished under this subsection shall supersede any State
10 law or regulation (other than State licensing laws or State
11 laws relating to plan solvency) with respect to Medicare Ad-
12 vantage plans which are offered by Medicare Advantage or-
13 ganizations under this part.”.

14 (b) EFFECTIVE DATE.—The amendment made by sub-
15 section (a) shall take effect on the date of the enactment of this
16 Act.

17 **SEC. 233. SPECIALIZED MEDICARE ADVANTAGE PLANS**
18 **FOR SPECIAL NEEDS BENEFICIARIES.**

19 (a) TREATMENT AS COORDINATED CARE PLAN.—Section
20 1851(a)(2)(A) (42 U.S.C. 1395w-21(a)(2)(A)) is amended by
21 adding at the end the following new sentence: “Specialized
22 Medicare Advantage plans for special needs beneficiaries (as
23 defined in section 1859(b)(4)) may be any type of coordinated
24 care plan.”.

25 (b) SPECIALIZED MEDICARE ADVANTAGE PLAN FOR SPE-
26 CIAL NEEDS BENEFICIARIES DEFINED.—Section 1859(b) (42
27 U.S.C. 1395w-29(b)) is amended by adding at the end the fol-
28 lowing new paragraph:

29 “(4) SPECIALIZED MEDICARE ADVANTAGE PLANS FOR
30 SPECIAL NEEDS BENEFICIARIES.—

31 “(A) IN GENERAL.—The term ‘specialized Medi-
32 care Advantage plan for special needs beneficiaries’
33 means a Medicare Advantage plan that exclusively
34 serves special needs beneficiaries (as defined in sub-
35 paragraph (B)).

1 “(B) SPECIAL NEEDS BENEFICIARY.—The term
2 ‘special needs beneficiary’ means a Medicare Advantage
3 eligible individual who—

4 “(i) is institutionalized (as defined by the Sec-
5 retary);

6 “(ii) is entitled to medical assistance under a
7 State plan under title XIX; or

8 “(iii) meets such requirements as the Sec-
9 retary may determine would benefit from enroll-
10 ment in such a specialized Medicare Advantage
11 plan described in subparagraph (A) for individuals
12 with severe or disabling chronic conditions.”.

13 (c) RESTRICTION ON ENROLLMENT PERMITTED.—Section
14 1859 (42 U.S.C. 1395w-29) is amended by adding at the end
15 the following new subsection:

16 “(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED
17 MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENE-
18 FICIARIES.—In the case of a specialized Medicare Advantage
19 plan (as defined in subsection (b)(4)), notwithstanding any
20 other provision of this part and in accordance with regulations
21 of the Secretary and for periods before January 1, 2007, the
22 plan may restrict the enrollment of individuals under the plan
23 to individuals who are within one or more classes of special
24 needs beneficiaries.”.

25 (d) REPORT TO CONGRESS.—Not later than December 31,
26 2005, the Medicare Benefits Administrator shall submit to
27 Congress a report that assesses the impact of specialized Medi-
28 care Advantage plans for special needs beneficiaries on the cost
29 and quality of services provided to enrollees. Such report shall
30 include an assessment of the costs and savings to the medicare
31 program as a result of amendments made by subsections (a),
32 (b), and (c).

33 (e) EFFECTIVE DATES.—

34 (1) IN GENERAL.—The amendments made by sub-
35 sections (a), (b), and (c) shall take effect upon the date of
36 the enactment of this Act.

1 (2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR
2 SPECIAL NEEDS BENEFICIARIES; TRANSITION.—No later
3 than 6 months after the date of the enactment of this Act,
4 the Secretary of Health and Human Services shall issue
5 final regulations to establish requirements for special needs
6 beneficiaries under section 1859(b)(4)(B)(iii) of the Social
7 Security Act, as added by subsection (b).

8 **SEC. 234. MEDICARE MSAS.**

9 (a) EXEMPTION FROM REPORTING ENROLLEE ENCOUN-
10 TER DATA.—

11 (1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C.
12 1395w-22(e)(1)) is amended by inserting “(other than
13 MSA plans)” after “plans”.

14 (2) CONFORMING AMENDMENTS.—Section 1852 (42
15 U.S.C. 1395w-22) is amended—

16 (A) in subsection (c)(1)(I), by inserting before the
17 period at the end the following: “if required under such
18 section”; and

19 (B) in subparagraphs (A) and (B) of subsection
20 (e)(2), by striking “, a non-network MSA plan,” and
21 “, NON-NETWORK MSA PLANS,” each place it appears.

22 (b) MAKING PROGRAM PERMANENT AND ELIMINATING
23 CAP.—Section 1851(b)(4) (42 U.S.C. 1395w-21(b)(4)) is
24 amended—

25 (1) in the heading, by striking “ON A DEMONSTRATION
26 BASIS”;

27 (2) by striking the first sentence of subparagraph (A);
28 and

29 (3) by striking the second sentence of subparagraph
30 (C).

31 (c) APPLYING LIMITATIONS ON BALANCE BILLING.—Sec-
32 tion 1852(k)(1) (42 U.S.C. 1395w-22(k)(1)) is amended by in-
33 serting “or with an organization offering a MSA plan” after
34 “section 1851(a)(2)(A)”.

35 (d) ADDITIONAL AMENDMENT.—Section 1851(e)(5)(A)
36 (42 U.S.C. 1395w-21(e)(5)(A)) is amended—

37 (1) by adding “or” at the end of clause (i);

1 (2) by striking “, or” at the end of clause (ii) and in-
2 serting a semicolon; and
3 (3) by striking clause (iii).

4 **SEC. 235. EXTENSION OF REASONABLE COST CON-**
5 **TRACTS.**

6 Subparagraph (C) of section 1876(h)(5) (42 U.S.C.
7 1395mm(h)(5)) is amended to read as follows:

8 “(C)(i) Subject to clause (ii), may be extended or renewed
9 under this subsection indefinitely.

10 “(ii) For any period beginning on or after January 1,
11 2008, a reasonable cost reimbursement contract under this sub-
12 section may not be extended or renewed for a service area inso-
13 far as such area, during the entire previous year, was within
14 the service area of 2 or more plans which were coordinated care
15 Medicare Advantage plans under part C or 2 or more enhanced
16 fee-for-service plans under part E and each of which plan for
17 that previous year for the area involved meets the following
18 minimum enrollment requirements:

19 “(I) With respect to any portion of the area involved
20 that is within a Metropolitan Statistical Area with a popu-
21 lation of more than 250,000 and counties contiguous to
22 such Metropolitan Statistical Area, 5,000 individuals.

23 “(II) With respect to any other portion of such area,
24 1,500 individuals.”.

25 **Subtitle C—Application of FEHBP-**
26 **Style Competitive Reforms**

27 **SEC. 241. APPLICATION OF FEHBP-STYLE COMPETITIVE**
28 **REFORM BEGINNING IN 2010.**

29 (a) IDENTIFICATION OF COMPETITIVE EFFS REGIONS;
30 COMPUTATION OF COMPETITIVE EFFS NON-DRUG BENCH-
31 MARKS UNDER EFFS PROGRAM.—

32 (1) IN GENERAL.—Section 1860E-3, as added by sec-
33 tion 201(a), is amended by adding at the end the following
34 new subsection:

35 “(e) APPLICATION OF COMPETITION.—

36 “(1) DETERMINATION OF COMPETITIVE EFFS RE-
37 GIONS.—

1 “(A) IN GENERAL.—For purposes of this part, the
2 term ‘competitive EFFS region’ means, for a year be-
3 ginning with 2010, an EFFS region that the Adminis-
4 trator finds—

5 “(i) there will be offered in the region during
6 the annual, coordinated election period under sec-
7 tion 1851(e)(3)(B) (as applied under section
8 1860E–1(c)) before the beginning of the year at
9 least 2 EFFS plans (in addition to the fee-for-serv-
10 ice program under parts A and B), each offered by
11 a different EFFS organization and each of which
12 met the minimum enrollment requirements of para-
13 graph (1) of section 1857(b) (as applied without
14 regard to paragraph (3) thereof) as of March of the
15 previous year; and

16 “(ii) during March of the previous year at
17 least the percentage specified in subparagraph (C)
18 of the number of EFFS eligible individuals who re-
19 side in the region were enrolled in an EFFS plan.

20 “(B) PERCENTAGE SPECIFIED.—

21 “(i) IN GENERAL.—For purposes of subpara-
22 graph (A), subject to clause (ii), the percentage
23 specified in this subparagraph for a year is equal
24 the lesser of 20 percent or to the sum of—

25 “(I) the percentage, as estimated by the
26 Administrator, of EFFS eligible individuals in
27 the United States who are enrolled in EFFS
28 plans during March of the previous year; and

29 “(II) the percentage, as estimated by the
30 Administrator, of Medicare Advantage eligible
31 individuals in the United States who are en-
32 rolled in Medicare Advantage plans during
33 March of the previous year.

34 “(ii) EXCEPTION.—In the case of an EFFS
35 region that was a competitive EFFS region for the
36 previous year, the Medicare Benefits Administrator
37 may continue to treat the region as meeting the re-

quirement of subparagraph (A)(ii) if the region would meet such requirement but for a de minimis reduction below the percentage specified in clause (i).

“(2) COMPETITIVE EFFS NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term ‘competitive EFFS non-drug monthly benchmark amount’ means, with respect to an EFFS region for a month in a year and subject to paragraph (8), the sum of the 2 components described in paragraph (3) for the region and year. The Administrator shall compute such benchmark amount for each competitive EFFS region before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which it is designated as such a region.

“(3) 2 COMPONENTS.—For purposes of paragraph (2), the 2 components described in this paragraph for an EFFS region and a year are the following:

“(A) EFFS COMPONENT.—The product of the following:

“(i) WEIGHTED AVERAGE OF PLAN BIDS IN REGION.—The weighted average of the EFFS plan bids for the region and year (as determined under paragraph (4)(A)).

“(ii) NON-FFS MARKET SHARE.—1 minus the fee-for-service market share percentage determined under paragraph (5) for the region and the year.

“(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:

“(i) FEE-FOR-SERVICE REGION-SPECIFIC NON-DRUG AMOUNT.—The fee-for-service region-specific non-drug amount (as defined in paragraph (6)) for the region and year.

“(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage (determined under paragraph (5)) for the region and the year.

1 “(4) DETERMINATION OF WEIGHTED AVERAGE EFFS
2 PLAN BIDS FOR A REGION.—

3 “(A) IN GENERAL.—For purposes of paragraph
4 (3)(A)(i), the weighted average of EFFS plan bids for
5 an EFFS region and a year is the sum of the following
6 products for EFFS plans described in subparagraph
7 (C) in the region and year:

8 “(i) UNADJUSTED EFFS STATUTORY NON-
9 DRUG MONTHLY BID AMOUNT.—The unadjusted
10 EFFS statutory non-drug monthly bid amount (as
11 defined in subsection (a)(3)(A)(ii)(I)) for the region
12 and year.

13 “(ii) PLAN’S SHARE OF EFFS ENROLLMENT IN
14 REGION.—The number of individuals described in
15 subparagraph (B), divided by the total number of
16 such individuals for all EFFS plans described in
17 subparagraph (C) for that region and year.

18 “(B) COUNTING OF INDIVIDUALS.—The Adminis-
19 trator shall count, for each EFFS plan described in
20 subparagraph (C) for an EFFS region and year, the
21 number of individuals who reside in the region and who
22 were enrolled under such plan under this part during
23 March of the previous year.

24 “(C) EXCLUSION OF PLANS NOT OFFERED IN PRE-
25 VIOUS YEAR.—For an EFFS region and year, the
26 EFFS plans described in this subparagraph are plans
27 that are offered in the region and year and were of-
28 fered in the region in March of the previous year.

29 “(5) COMPUTATION OF FEE-FOR-SERVICE MARKET
30 SHARE PERCENTAGE.—The Administrator shall determine,
31 for a year and an EFFS region, the proportion (in this
32 subsection referred to as the ‘fee-for-service market share
33 percentage’) of the EFFS eligible individuals who are resi-
34 dents of the region during March of the previous year, of
35 such individuals who were not enrolled in an EFFS plan
36 or in a Medicare Advantage plan (or, if greater, such pro-
37 portion determined for individuals nationally).

1 “(6) FEE-FOR-SERVICE REGION-SPECIFIC NON-DRUG
2 AMOUNT.—

3 “(A) IN GENERAL.—For purposes of paragraph
4 (3)(B)(i) and section 1839(h)(2)(A), subject to sub-
5 paragraph (B), the term ‘fee-for-service region-specific
6 non-drug amount’ means, for a competitive EFFS re-
7 gion and a year, the adjusted average per capita cost
8 for the year involved, determined under section
9 1876(a)(4) for such region for services covered under
10 parts A and B for individuals entitled to benefits under
11 part A and enrolled under this part who are not en-
12 rolled in an EFFS plan under part E or a Medicare
13 Advantage plan under part C for the year, but adjusted
14 to exclude costs attributable to payments under section
15 1886(h).

16 “(B) INCLUSION OF COSTS OF VA AND DOD MILI-
17 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE
18 BENEFICIARIES.—In determining the adjusted average
19 per capita cost under subparagraph (A) for a year,
20 such cost shall be adjusted to include the Administra-
21 tor’s estimate, on a per capita basis, of the amount of
22 additional payments that would have been made in the
23 region involved under this title if individuals entitled to
24 benefits under this title had not received services from
25 facilities of the Department of Veterans Affairs or the
26 Department of Defense.

27 “(7) APPLICATION OF COMPETITION.—In the case of
28 an EFFS region that is a competitive EFFS region for a
29 year, for purposes of applying subsections (b) and (c)(1)
30 and section 1860E-4(a), any reference to an EFFS region-
31 specific non-drug monthly benchmark amount shall be
32 treated as a reference to the competitive EFFS non-drug
33 monthly benchmark amount under paragraph (2) for the
34 region and year.

35 “(8) PHASE-IN OF BENCHMARK FOR EACH REGION.—

36 “(A) USE OF BLENDED BENCHMARK.—In the case
37 of a region that has not been a competitive EFFS re-

1 gion for each of the previous 4 years, the competitive
2 FFFS non-drug monthly benchmark amount shall be
3 equal to the sum of the following:

4 “(i) NEW COMPETITIVE COMPONENT.—The
5 product of—

6 “(I) the weighted average phase-in propor-
7 tion for that area and year, as specified in sub-
8 paragraph (B); and

9 “(II) the competitive EFFS non-drug
10 monthly benchmark amount for the region and
11 year, determined under paragraph (2) without
12 regard to this paragraph.

13 “(ii) OLD COMPETITIVE COMPONENT.—The
14 product of—

15 “(I) 1 minus the weighted average phase-
16 in proportion for that region and year; and

17 “(II) the EFFS region-specific non-drug
18 benchmark amount for the area and the year.

19 “(B) COMPUTATION OF WEIGHTED AVERAGE
20 PHASE-IN PROPORTION.—For purposes of this para-
21 graph, the ‘weighted average phase-in proportion’ for
22 an EFFS region for a year shall be determined as fol-
23 lows:

24 “(i) FIRST YEAR (AND REGION NOT COMPETI-
25 TIVE REGION IN PREVIOUS YEAR).—If the area was
26 not a competitive EFFS region in the previous
27 year, the weighted average phase-in proportion for
28 the region for the year is equal to $\frac{1}{5}$.

29 “(ii) COMPETITIVE REGION IN PREVIOUS
30 YEAR.—If the region was a competitive EFFS re-
31 gion in the previous year, the weighted average
32 phase-in proportion for the region for the year is
33 equal to the weighted average phase-in proportion
34 determined under this subparagraph for the region
35 for the previous year plus $\frac{1}{5}$, but in no case more
36 than 1.”.

37 (2) CONFORMING AMENDMENTS.—

1 (A) Such section 1860E-3 is further amended—
2 (i) in subsection (b), by adding at the end the
3 following new paragraph:

4 “(4) APPLICATION IN COMPETITIVE REGIONS.—
5 For special rules applying this subsection in competi-
6 tive EFFE regions, see subsection (e)(7).”;

7 (ii) in subsection (c)(1), by inserting “and
8 subsection (e)(7)” after “(as made applicable under
9 subsection (d))”; and

10 (iii) in subsection (d) , by striking “and (e)”
11 and inserting “(e), and (k) ”.

12 (B) Section 1860E-4(a)(1), as inserted by section
13 201(a)(2), is amended by inserting “, except as pro-
14 vided in section 1860E-3(e)(7)” after “paragraph (2)”.

15 I22 (b) IDENTIFICATION OF COMPETITIVE AREAS; APPLI-
16 CATION OF COMPETITIVE MEDICARE ADVANTAGE NON-DRUG
17 BENCHMARKS UNDER MEDICARE ADVANTAGE PROGRAM.—

18 (1) IN GENERAL.—Section 1853, as amended by sec-
19 tion 221(b)(3), is amended by adding at the end the fol-
20 lowing new subsection:

21 “(k) APPLICATION OF COMPETITION.—

22 “(1) DETERMINATION OF COMPETITIVE MEDICARE AD-
23 VANTAGE AREAS.—

24 “(A) IN GENERAL.—For purposes of this part, the
25 terms ‘competitive Medicare Advantage area’ and ‘CMA
26 area’ mean, for a year beginning with 2010, an area
27 (which is a metropolitan statistical area or other area
28 with a substantial number of Medicare Advantage en-
29 rollees) that the Administrator finds—

30 “(i) there will be offered during the annual,
31 coordinated election period under section
32 1851(e)(3)(B) under this part before the beginning
33 of the year at least 2 Medicare Advantage plans (in
34 addition to the fee-for-service program under parts
35 A and B), each offered by a different Medicare Ad-
36 vantage organization and each of which met the
37 minimum enrollment requirements of paragraph

1 (1) of section 1857(b) (as applied without regard
2 to paragraph (3) thereof) as of March of the pre-
3 vious year with respect to the area; and

4 “(ii) during March of the previous year at
5 least the percentage specified in subparagraph (B)
6 of the number of Medicare Advantage eligible indi-
7 viduals who reside in the area were enrolled in a
8 Medicare Advantage plan.

9 “(B) PERCENTAGE SPECIFIED.—

10 “(i) IN GENERAL.—For purposes of subpara-
11 graph (A), subject to clause (ii), the percentage
12 specified in this subparagraph for a year is equal
13 the lesser of 20 percent or to the sum of—

14 “(I) the percentage, as estimated by the
15 Administrator, of EFFS eligible individuals in
16 the United States who are enrolled in EFFS
17 plans during March of the previous year; and

18 “(II) the percentage, as estimated by the
19 Administrator, of Medicare Advantage eligible
20 individuals in the United States who are en-
21 rolled in Medicare Advantage plans during
22 March of the previous year.

23 “(ii) EXCEPTION.—In the case of an area that
24 was a competitive area for the previous year, the
25 Medicare Benefits Administrator may continue to
26 treat the area as meeting the requirement of sub-
27 paragraph (A)(ii) if the area would meet such re-
28 quirement but for a de minimis reduction below the
29 percentage specified in clause (i).

30 “(2) COMPETITIVE MEDICARE ADVANTAGE NON-DRUG
31 MONTHLY BENCHMARK AMOUNT.—For purposes of this
32 part, the term ‘competitive Medicare Advantage non-drug
33 monthly benchmark amount’ means, with respect to a com-
34 petitive Medicare Advantage area for a month in a year
35 subject to paragraph (8), the sum of the 2 components de-
36 scribed in paragraph (3) for the area and year. The Admin-
37 istrator shall compute such benchmark amount for each

1 competitive Medicare Advantage area before the beginning
2 of each annual, coordinated election period under section
3 1851(e)(3)(B) for each year (beginning with 2010) in
4 which it is designated as such an area.

5 “(3) 2 COMPONENTS.—For purposes of paragraph (2),
6 the 2 components described in this paragraph for a com-
7 petitive Medicare Advantage area and a year are the fol-
8 lowing:

9 “(A) MEDICARE ADVANTAGE COMPONENT.—The
10 product of the following:

11 “(i) WEIGHTED AVERAGE OF MEDICARE AD-
12 VANTAGE PLAN BIDS IN AREA.—The weighted aver-
13 age of the plan bids for the area and year (as de-
14 termined under paragraph (4)(A)).

15 “(ii) NON-FFS MARKET SHARE.—1 minus the
16 fee-for-service market share percentage, determined
17 under paragraph (5) for the area and year.

18 “(B) FEE-FOR-SERVICE COMPONENT.—The prod-
19 uct of the following:

20 “(i) FEE-FOR-SERVICE AREA-SPECIFIC NON-
21 DRUG AMOUNT.—The fee-for-service area-specific
22 non-drug amount (as defined in paragraph (6)) for
23 the area and year.

24 “(ii) FEE-FOR-SERVICE MARKET SHARE.—The
25 fee-for-service market share percentage, determined
26 under paragraph (5) for the area and year.

27 “(4) DETERMINATION OF WEIGHTED AVERAGE MEDI-
28 CARE ADVANTAGE BIDS FOR AN AREA.—

29 “(A) IN GENERAL.—For purposes of paragraph
30 (3)(A)(i), the weighted average of plan bids for an area
31 and a year is the sum of the following products for
32 Medicare Advantage plans described in subparagraph
33 (C) in the area and year:

34 “(i) MONTHLY MEDICARE ADVANTAGE STATU-
35 TORY NON-DRUG BID AMOUNT.—The unadjusted
36 Medicare Advantage statutory non-drug monthly
37 bid amount.

1 “(ii) PLAN’S SHARE OF MEDICARE ADVANTAGE
2 ENROLLMENT IN AREA.—The number of individ-
3 uals described in subparagraph (B), divided by the
4 total number of such individuals for all Medicare
5 Advantage plans described in subparagraph (C) for
6 that area and year.

7 “(B) COUNTING OF INDIVIDUALS.—The Adminis-
8 trator shall count, for each Medicare Advantage plan
9 described in subparagraph (C) for an area and year,
10 the number of individuals who reside in the area and
11 who were enrolled under such plan under this part dur-
12 ing March of the previous year.

13 “(C) EXCLUSION OF PLANS NOT OFFERED IN PRE-
14 VIOUS YEAR.—For an area and year, the Medicare Ad-
15 vantage plans described in this subparagraph are plans
16 described in the first sentence of section 1851(a)(2)(A)
17 that are offered in the area and year and were offered
18 in the area in March of the previous year.

19 “(5) COMPUTATION OF FEE-FOR-SERVICE MARKET
20 SHARE PERCENTAGE.—The Administrator shall determine,
21 for a year and a competitive Medicare Advantage area, the
22 proportion (in this subsection referred to as the ‘fee-for-
23 service market share percentage’) of Medicare Advantage
24 eligible individuals residing in the area who during March
25 of the previous year were not enrolled in a Medicare Advan-
26 tage plan or in an EFFS plan (or, if greater, such propor-
27 tion determined for individuals nationally).

28 “(6) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG
29 AMOUNT.—

30 “(A) IN GENERAL.—For purposes of paragraph
31 (3)(B)(i) and section 1839(h)(1)(A), subject to sub-
32 paragraph (B), the term ‘fee-for-service area-specific
33 non-drug amount’ means, for a competitive Medicare
34 Advantage area and a year, the adjusted average per
35 capita cost for the year involved, determined under sec-
36 tion 1876(a)(4) for such area for services covered
37 under parts A and B for individuals entitled to benefits

1 under part A and enrolled under this part who are not
2 enrolled in a Medicare Advantage plan under part C or
3 an EFS plan under part E for the year, but adjusted
4 to exclude costs attributable to payments under section
5 1886(h).

6 “(B) INCLUSION OF COSTS OF VA AND DOD MILI-
7 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE
8 BENEFICIARIES.—In determining the adjusted average
9 per capita cost under subparagraph (A) for a year,
10 such cost shall be adjusted to include the Administra-
11 tor’s estimate, on a per capita basis, of the amount of
12 additional payments that would have been made in the
13 area involved under this title if individuals entitled to
14 benefits under this title had not received services from
15 facilities of the Department of Veterans Affairs or the
16 Department of Defense.

17 “(7) APPLICATION OF COMPETITION.—In the case of
18 an area that is a competitive Medicare Advantage area for
19 a year, for purposes of applying subsection (a)(1)(A)(ii)
20 and sections 1854(b)(2)(A)(ii) and 1854(b)(3)(B)(i), any
21 reference to a Medicare Advantage area-specific non-drug
22 monthly benchmark amount shall be treated as a reference
23 to the competitive Medicare Advantage non-drug monthly
24 benchmark amount under paragraph (2) for the area and
25 year.

26 “(8) PHASE-IN OF BENCHMARK FOR EACH AREA.—

27 “(A) USE OF BLENDED BENCHMARK.—In the case
28 of an area that has not been a competitive Medicare
29 Advantage area for each of the previous 5 years, the
30 competitive Medicare Advantage non-drug monthly
31 benchmark amount shall be equal to the sum of the fol-
32 lowing:

33 “(i) NEW COMPETITIVE COMPONENT.—The
34 product of—

35 “(I) the weighted average phase-in propor-
36 tion for that area and year, as specified in sub-
37 paragraph (B); and

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1 “(II) the competitive Medicare Advantage
2 non-drug monthly benchmark amount for the
3 area and year, determined under paragraph (2)
4 without regard to this paragraph.

5 “(ii) OLD COMPETITIVE COMPONENT.—The
6 product of—

7 “(I) 1 minus the weighted average phase-
8 in proportion for that area and year; and

9 “(II) the Medicare Advantage area-wide
10 non-drug benchmark amount for the area and
11 the year.

12 “(B) COMPUTATION OF WEIGHTED AVERAGE
13 PHASE-IN PROPORTION.—For purposes of this para-
14 graph, the ‘weighted average phase-in proportion’ for a
15 Medicare Advantage payment area for a year shall be
16 determined as follows:

17 “(i) FIRST YEAR (AND AREA NOT COMPETI-
18 TIVE AREA IN PREVIOUS YEAR).—If the area was
19 not a Medicare Advantage competitive area in the
20 previous year, the weighted average phase-in pro-
21 portion for the area for the year is equal to $\frac{1}{5}$.

22 “(ii) COMPETITIVE AREA IN PREVIOUS
23 YEAR.—If the area was a competitive Medicare Ad-
24 vantage area in the previous year, the weighted av-
25 erage phase-in proportion for the area for the year
26 is equal to the weighted average phase-in propor-
27 tion determined under this subparagraph for the
28 area for the previous year plus $\frac{1}{5}$, but in no case
29 more than 1.

30 “(C) MEDICARE ADVANTAGE AREA-WIDE NON-
31 DRUG BENCHMARK AMOUNT.—For purposes of sub-
32 paragraph (A)(ii)(II), the term ‘Medicare Advantage
33 area-wide non-drug benchmark amount’ means, for an
34 area and year, the weighted average of the amounts de-
35 scribed in section 1853(j) for Medicare Advantage pay-
36 ment area or areas included in the area (based on the

1 number of traditional fee-for-service enrollees in such
2 payment area or areas) and year.”.

3 (2) APPLICATION.—Section 1854 (42 U.S.C. 1395w-
4 24) is amended—

5 (A) in subsection (b)(1)(C)(i), as added by section
6 221(b)(1)(A), by striking “(i) REQUIREMENT.—The”
7 and inserting “(i) REQUIREMENT FOR NON-COMPETI-
8 TIVE AREAS.—In the case of a Medicare Advantage
9 payment area that is not a competitive Medicare Ad-
10 vantage area designated under section 1853(k)(1),
11 the”;

12 (B) in subsection (b)(1)(C), as so added, by insert-
13 ing after clause (i) the following new clause:

14 “(ii) REQUIREMENT FOR COMPETITIVE MEDI-
15 CARE ADVANTAGE AREAS.—In the case of a Medi-
16 care Advantage payment area that is designated as
17 a competitive Medicare Advantage area under sec-
18 tion 1853(k)(1), if there are average per capita
19 monthly savings described in paragraph (6) for a
20 Medicare Advantage plan and year, the Medicare
21 Advantage plan shall provide to the enrollee a
22 monthly rebate equal to 75 percent of such sav-
23 ings.”; and

24 (C) by adding at the end of subsection (b), as
25 amended by sections 221(b)(1)(B) and 221(b)(2), the
26 following new paragraph:

27 “(6) COMPUTATION OF AVERAGE PER CAPITA MONTH-
28 LY SAVINGS FOR COMPETITIVE MEDICARE ADVANTAGE
29 AREAS.—For purposes of paragraph (1)(C)(ii), the average
30 per capita monthly savings referred to in such paragraph
31 for a Medicare Advantage plan and year shall be computed
32 in the same manner as the average per capita monthly sav-
33 ings is computed under paragraph (3) except that the ref-
34 erence to the Medicare Advantage area-specific non-drug
35 monthly benchmark amount in paragraph (3)(B)(i) (or to
36 the benchmark amount as adjusted under paragraph
37 (3)(C)(i)) is deemed to be a reference to the competitive

1 Medicare Advantage non-drug monthly benchmark amount
2 (or such amount as adjusted in the manner described in
3 paragraph (3)(B)(i)).”.

4 (3) ADDITIONAL CONFORMING AMENDMENTS.—

5 (A) PAYMENT OF PLANS.—Section
6 1853(a)(1)(A)(ii), as amended by section 221(c)(1), is
7 amended—

8 (i) in subclauses (I) and (II), by inserting
9 “(or, insofar as such payment area is a competitive
10 Medicare Advantage area, described in section
11 1854(b)(6))” after “section 1854(b)(3)(C)”; and

12 (ii) in subclause (II), by inserting “(or, insofar
13 as such payment area is a competitive Medicare
14 Advantage area, the competitive Medicare Advan-
15 tage non-drug monthly benchmark amount)” after
16 “Medicare Advantage area-specific non-drug
17 monthly benchmark amount”; and

18 (B) DISCLOSURE OF INFORMATION.—Section
19 1853(b)(1)(B), as amended by section 221(e)(1), is
20 amended to read as follows:

21 “(B) COMPETITION INFORMATION.—For years be-
22 ginning with 2006, the following:

23 “(i) BENCHMARKS.—The Medicare Advantage
24 area-specific non-drug benchmark under section
25 1853(j) and, if applicable, the competitive Medicare
26 Advantage non-drug benchmark under section
27 1853(k)(2), for the year and competitive Medicare
28 Advantage area involved and the national fee-for-
29 service market share percentage for the area and
30 year.

31 “(ii) ADJUSTMENT FACTORS.—The adjust-
32 ment factors applied under section
33 1853(a)(1)(A)(iv) (relating to demographic adjust-
34 ment), section 1853(a)(1)(B) (relating to adjust-
35 ment for end-stage renal disease), and section
36 1853(a)(3) (relating to health status adjustment).

1 “(iii) CERTAIN BENCHMARKS AND
2 AMOUNTS.—In the case of a competitive Medicare
3 Advantage area, the Medicare Advantage area-wide
4 non-drug benchmark amount (as defined in sub-
5 section (k)(8)(C)) and the fee-for-service area-spe-
6 cific non-drug amount (as defined in section
7 1853(k)(6)) for the area.

8 “(iv) INDIVIDUALS.—The number of individ-
9 uals counted under subsection (k)(4)(B) and en-
10 rolled in each Medicare Advantage plan in the
11 area.”.

12 (C) DEFINITION OF MONTHLY BASIC PREMIUM.—
13 Section 1854(b)(2)(A)(ii), as amended by section
14 221(d)(2), is amended by inserting “(or, in the case of
15 a competitive Medicare Advantage area, the competitive
16 Medicare Advantage non-drug monthly benchmark
17 amount or, in applying this paragraph under part E in
18 the case of a competitive EFFS region, the competitive
19 EFFS non-drug monthly benchmark amount)” after
20 “benchmark amount”.

21 (c) PREMIUM ADJUSTMENT.—

22 (1) IN GENERAL.—Section 1839 (42 U.S.C. 1395r) is
23 amended by adding at the end the following new sub-
24 section:

25 “(h)(1)(A) In the case of an individual who resides in a
26 competitive Medicare Advantage area under section 1853(k)(1)
27 (regardless of whether such area is in a competitive EFFS re-
28 gion under section 1860E-3(e)) and who is not enrolled in a
29 Medicare Advantage plan under part C or in an EFFS plan
30 under part E, the monthly premium otherwise applied under
31 this part (determined without regard to subsections (b) and (f)
32 or any adjustment under this subsection) shall be adjusted as
33 follows: If the fee-for-service area-specific non-drug amount (as
34 defined in section 1853(k)(6)) for the competitive Medicare Ad-
35 vantage area in which the individual resides for a month—

36 “(i) does not exceed the competitive Medicare Advan-
37 tage non-drug benchmark (as determined under section

1 1853(k)(2)) for such area, the amount of the premium for
2 the individual for the month shall be reduced by an amount
3 equal to the product of the adjustment factor under sub-
4 paragraph (C) and 75 percent of the amount by which such
5 competitive benchmark exceeds such fee-for-service area-
6 specific non-drug amount; or

7 “(ii) exceeds such competitive Medicare Advantage
8 non-drug benchmark, the amount of the premium for the
9 individual for the month shall be adjusted to ensure, sub-
10 ject to subparagraph (B), that—

11 “(I) the sum of the amount of the adjusted pre-
12 mium and the competitive Medicare Advantage non-
13 drug benchmark for the area, is equal to

14 “(II) the sum of the unadjusted premium plus
15 amount of the fee-for-service area-specific non-drug
16 amount for the area.

17 “(B) In no case shall the actual amount of an adjustment
18 under subparagraph (A)(ii) exceed the product of the adjust-
19 ment factor under subparagraph (C) and the amount of the ad-
20 justment otherwise computed under subparagraph (A)(ii) with-
21 out regard to this subparagraph.

22 “(C) The adjustment factor under this subparagraph for
23 an area for a year is equal to—

24 “(i) the number of consecutive years (in the 5-year pe-
25 riod ending with the year involved) in which such area was
26 a competitive Medicare Advantage area; divided by

27 “(ii) 5.

28 “(2)(A) In the case of an individual who resides in an area
29 that is within a competitive EFFS region under section
30 1860E-3(e) but is not within a competitive Medicare Advan-
31 tage area under section 1853(k)(1) and who is not enrolled in
32 a Medicare Advantage plan under part C or in an EFFS plan
33 under part E, the monthly premium otherwise applied under
34 this part (determined without regard to subsections (b) and (f)
35 or any adjustment under this subsection) shall be adjusted as
36 follows: If the fee-for-service region-specific non-drug amount

1 (as defined in section 1860E-3(e)(6)) for a region for a
2 month—

3 “(i) does not exceed the competitive EFFS non-drug
4 monthly benchmark amount (as determined under section
5 1860E-3(e)(2)) for such region, the amount of the pre-
6 mium for the individual for the month shall be reduced by
7 an amount equal to the product of the adjustment factor
8 under subparagraph (C) and 75 percent of the amount by
9 which such competitive benchmark amount exceeds such
10 fee-for-service region-specific non-drug benchmark amount;
11 or

12 “(ii) exceeds such competitive EFFS non-drug month-
13 ly benchmark amount, the amount of the premium for the
14 individual for the month shall be adjusted to ensure, sub-
15 ject to subparagraph (B), that—

16 “(I) the sum of the amount of the adjusted pre-
17 mium and the competitive EFFS non-drug monthly
18 benchmark amount for the region, is equal to

19 “(II) the sum of the unadjusted premium plus the
20 amount of the EFFS region-specific non-drug monthly
21 bidfor the region.

22 “(B) In no case shall the actual amount of an adjustment
23 under subparagraph (A)(ii) exceed the product of the adjust-
24 ment factor under subparagraph (C) and the amount of the ad-
25 justment otherwise computed under subparagraph (A)(ii) with-
26 out regard to this subparagraph.

27 “(C) The adjustment factor under this subparagraph for
28 an EFFS region for a year is equal to—

29 “(i) the number of consecutive years (in the 5-year pe-
30 riod ending with the year involved) in which such region
31 was a competitive EFFS region; divided by

32 “(ii) 5.

33 “(3) Nothing in this subsection shall be construed as pre-
34 venting a reduction under paragraph (1)(A) or paragraph
35 (2)(A) in the premium otherwise applicable under this part to
36 zero or from requiring the provision of a rebate to the extent
37 such premium would otherwise be required to be less than zero.

1 “(4) The adjustment in the premium under this subsection
2 shall be effected in such manner as the Medicare Benefits Ad-
3 ministrator determines appropriate.

4 “(5) In order to carry out this subsection (insofar as it is
5 effected through the manner of collection of premiums under
6 1840(a)), the Medicare Benefits Administrator shall transmit
7 to the Commissioner of Social Security—

8 “(A) at the beginning of each year, the name, social
9 security account number, and the amount of the adjust-
10 ment (if any) under this subsection for each individual en-
11 rolled under this part for each month during the year; and

12 “(B) periodically throughout the year, information to
13 update the information previously transmitted under this
14 paragraph for the year.”.

15 (2) CONFORMING AMENDMENT.—Section 1844(c) (42
16 U.S.C. 1395w(c)) is amended by inserting “and without re-
17 gard to any premium adjustment effected under section
18 1839(h)” before the period at the end.

19 (d) EFFECTIVE DATE.—The amendments made by this
20 section shall take effect on January 1, 2010.

21 **TITLE III—COMBATTING WASTE,** 22 **FRAUD, AND ABUSE**

23 **SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVI-** 24 **SIONS.**

25 (a) TECHNICAL AMENDMENT CONCERNING SECRETARY’S
26 AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CER-
27 TAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—

28 (1) IN GENERAL.—Section 1862(b)(2) (42 U.S.C.
29 1395y(b)(2)) is amended—

30 (A) in subparagraph (A)(ii), by striking “promptly
31 (as determined in accordance with regulations)”;

32 (B) in subparagraph (B)—

33 (i) by redesignating clauses (i) through (iii) as
34 clauses (ii) through (iv), respectively; and

35 (ii) by inserting before clause (ii), as so redes-
36 ignated, the following new clause:

1 “(i) AUTHORITY TO MAKE CONDITIONAL PAY-
2 MENT.—The Secretary may make payment under
3 this title with respect to an item or service if a pri-
4 mary plan described in subparagraph (A)(ii) has
5 not made or cannot reasonably be expected to make
6 payment with respect to such item or service
7 promptly (as determined in accordance with regula-
8 tions). Any such payment by the Secretary shall be
9 conditioned on reimbursement to the appropriate
10 Trust Fund in accordance with the succeeding pro-
11 visions of this subsection.”.

12 (2) EFFECTIVE DATE.—The amendments made by
13 paragraph (1) shall be effective as if included in the enact-
14 ment of title III of the Medicare and Medicaid Budget Rec-
15 onciliation Amendments of 1984 (Public Law 98-369).

16 (b) CLARIFYING AMENDMENTS TO CONDITIONAL PAY-
17 MENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C.
18 1395y(b)(2)) is further amended—

19 (1) in subparagraph (A), in the matter following
20 clause (ii), by inserting the following sentence at the end:
21 “An entity that engages in a business, trade, or profession
22 shall be deemed to have a self-insured plan if it carries its
23 own risk (whether by a failure to obtain insurance, or oth-
24 erwise) in whole or in part.”;

25 (2) in subparagraph (B)(ii), as redesignated by sub-
26 section (a)(2)(B)—

27 (A) by striking the first sentence and inserting the
28 following: “A primary plan, and an entity that receives
29 payment from a primary plan, shall reimburse the ap-
30 propriate Trust Fund for any payment made by the
31 Secretary under this title with respect to an item or
32 service if it is demonstrated that such primary plan has
33 or had a responsibility to make payment with respect
34 to such item or service. A primary plan’s responsibility
35 for such payment may be demonstrated by a judgment,
36 a payment conditioned upon the recipient’s com-
37 promise, waiver, or release (whether or not there is a

determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means."; and

(B) in the final sentence, by striking "on the date such notice or other information is received" and inserting "on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received"; and

(3) in subparagraph (B)(iii), , as redesignated by subsection (a)(2)(B), by striking the first sentence and inserting the following: "In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity.".

(c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C. 1395y(b)) is amended—

(1) in paragraph (1)(A), by moving the indentation of clauses (ii) through (v) 2 ems to the left; and

(2) in paragraph (3)(A), by striking "such" before "paragraphs".

SEC. 302. COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) IN GENERAL.—Section 1847 (42 U.S.C. 1395w-3) is amended to read as follows:

1 “COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES
2 “SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE AC-
3 QUISSION PROGRAMS.—

4 “(1) IMPLEMENTATION OF PROGRAMS.—

5 “(A) IN GENERAL.—The Secretary shall establish
6 and implement programs under which competitive ac-
7 quisition areas are established throughout the United
8 States for contract award purposes for the furnishing
9 under this part of competitively priced items and serv-
10 ices (described in paragraph (2)) for which payment is
11 made under this part. Such areas may differ for dif-
12 ferent items and services.

13 “(B) PHASED-IN IMPLEMENTATION.—The pro-
14 grams shall be phased-in—

15 “(i) among competitive acquisition areas over
16 a period of not longer than 3 years in a manner
17 so that the competition under the programs occurs
18 in—

19 “(I) at least $\frac{1}{3}$ of such areas in 2005; and

20 “(II) at least $\frac{2}{3}$ of such areas in 2006;

21 and

22 “(ii) among items and services in a manner
23 such that the programs apply to the highest cost
24 and highest volume items and services first.

25 “(C) WAIVER OF CERTAIN PROVISIONS.—In car-
26 rying out the programs, the Secretary may waive such
27 provisions of the Federal Acquisition Regulation as are
28 necessary for the efficient implementation of this sec-
29 tion, other than provisions relating to confidentiality of
30 information and such other provisions as the Secretary
31 determines appropriate.

32 “(2) ITEMS AND SERVICES DESCRIBED.—The items
33 and services referred to in paragraph (1) are the following:

34 “(A) DURABLE MEDICAL EQUIPMENT AND MED-
35 ICAL SUPPLIES.—Covered items (as defined in section
36 1834(a)(13)) for which payment is otherwise made
37 under section 1834(a), including items used in infusion

1 and drugs and supplies used in conjunction with dura-
2 ble medical equipment, but excluding class III devices
3 under the Federal Food, Drug, and Cosmetic Act.

4 “(B) OFF-THE-SHELF ORTHOTICS.—Orthotics (de-
5 scribed in section 1861(s)(9)) for which payment is
6 otherwise made under section 1834(h) which require
7 minimal self-adjustment for appropriate use and does
8 not require expertise in trimming, bending, molding,
9 assembling, or customizing to fit to the patient.

10 “(3) EXCEPTION AUTHORITY.—In carrying out the
11 programs under this section, the Secretary may exempt—

12 “(A) rural areas and areas with low population
13 density within urban areas that are not competitive,
14 unless there is a significant national market through
15 mail order for a particular item or service; and

16 “(B) items and services for which the application
17 of competitive acquisition is not likely to result in sig-
18 nificant savings.

19 “(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF
20 DURABLE MEDICAL EQUIPMENT.—In the case of a covered
21 item for which payment is made on a rental basis under
22 section 1834(a), the Secretary shall establish a process by
23 which rental agreements for the covered items entered into
24 before the application of the competitive acquisition pro-
25 gram under this section for the item may be continued not-
26 withstanding this section. In the case of any such continu-
27 ation, the supplier involved shall provide for appropriate
28 servicing and replacement, as required under section
29 1834(a).

30 “(5) PHYSICIAN AUTHORIZATION.—The Secretary may
31 establish a process under which a physician may prescribe
32 a particular brand or mode of delivery of an item or service
33 if the item or service involved is clinically more appropriate
34 than other similar items or services.

35 “(6) APPLICATION.—For each competitive acquisition
36 area in which the program is implemented under this sub-
37 section with respect to items and services, the payment

1 basis determined under the competition conducted under
2 subsection (b) shall be substituted for the payment basis
3 otherwise applied under section 1834(a).

4 “(b) PROGRAM REQUIREMENTS.—

5 “(1) IN GENERAL.—The Secretary shall conduct a
6 competition among entities supplying items and services de-
7 scribed in subsection (a)(2) for each competitive acquisition
8 area in which the program is implemented under subsection
9 (a) with respect to such items and services.

10 “(2) CONDITIONS FOR AWARDED CONTRACT.—

11 “(A) IN GENERAL.—The Secretary may not award
12 a contract to any entity under the competition con-
13 ducted in an competitive acquisition area pursuant to
14 paragraph (1) to furnish such items or services unless
15 the Secretary finds all of the following:

16 “(i) The entity meets quality and financial
17 standards specified by the Secretary or developed
18 by the Program Advisory and Oversight Committee
19 established under subsection (c).

20 “(ii) The total amounts to be paid under the
21 contract (including costs associated with the ad-
22 ministration of the contract) are expected to be less
23 than the total amounts that would otherwise be
24 paid.

25 “(iii) Beneficiary access to a choice of multiple
26 suppliers in the area is maintained.

27 “(iv) Beneficiary liability is limited to 20 per-
28 cent of the applicable contract award price, except
29 in such cases where a supplier has furnished an up-
30 graded item and has executed an advanced bene-
31 ficiary notice.

32 “(B) DEVELOPMENT OF QUALITY STANDARDS FOR
33 DME PRODUCTS.—

34 “(i) IN GENERAL.—The quality standards
35 specified under subparagraph (A)(i) shall not be
36 less than the quality standards that would other-
37 wise apply if this section did not apply and shall

1 include consumer services standards. Not later than
2 July 1, 2004, the Secretary shall establish new
3 quality standards for products subject to competi-
4 tive acquisition under this section. Such standards
5 shall be applied prospectively and shall be published
6 on the website of the Department of Health and
7 Human Services.

8 “(ii) CONSULTATION WITH PROGRAM ADVI-
9 SORY AND OVERSIGHT COMMITTEE.—The Secretary
10 shall consult with the Program Advisory and Over-
11 sight Committee (established under subsection (c))
12 to review (and advise the Secretary concerning) the
13 quality standards referred to in clause (i).

14 “(3) CONTENTS OF CONTRACT.—

15 “(A) IN GENERAL.—A contract entered into with
16 an entity under the competition conducted pursuant to
17 paragraph (1) is subject to terms and conditions that
18 the Secretary may specify.

19 “(B) TERM OF CONTRACTS.—The Secretary shall
20 recompile contracts under this section not less often
21 than once every 3 years.

22 “(4) LIMIT ON NUMBER OF CONTRACTORS.—

23 “(A) IN GENERAL.—The Secretary may limit the
24 number of contractors in a competitive acquisition area
25 to the number needed to meet projected demand for
26 items and services covered under the contracts. In
27 awarding contracts, the Secretary shall take into ac-
28 count the ability of bidding entities to furnish items or
29 services in sufficient quantities to meet the anticipated
30 needs of beneficiaries for such items or services in the
31 geographic area covered under the contract on a timely
32 basis.

33 “(B) MULTIPLE WINNERS.—The Secretary shall
34 award contracts to multiple entities submitting bids in
35 each area for an item or service.

36 “(5) PAYMENT.—Payment under this part for com-
37 petitively priced items and services described in subsection

1 (a)(2) shall be based on the bids submitted and accepted
2 under this section for such items and services.

3 “(6) PARTICIPATING CONTRACTORS.—Payment shall
4 not be made for items and services described in subsection
5 (a)(2) furnished by a contractor and for which competition
6 is conducted under this section unless—

7 “(A) the contractor has submitted a bid for such
8 items and services under this section; and

9 “(B) the Secretary has awarded a contract to the
10 contractor for such items and services under this sec-
11 tion.

12 In this section, the term ‘bid’ means a request for a pro-
13 posal for an item or service that includes the cost of the
14 item or service, and where appropriate, any services that
15 are attendant to the provision of the item or service.

16 “(7) CONSIDERATION IN DETERMINING CATEGORIES
17 FOR BIDS.—The Secretary shall consider the similarity of
18 the clinical efficiency and value of specific codes and prod-
19 ucts, including products that may provide a therapeutic ad-
20 vantage to beneficiaries, before delineating the categories
21 and products that will be subject to bidding.

22 “(8) AUTHORITY TO CONTRACT FOR EDUCATION, MON-
23 ITORING, OUTREACH AND COMPLAINT SERVICES.—The Sec-
24 retary may enter into a contract with an appropriate entity
25 to address complaints from beneficiaries who receive items
26 and services from an entity with a contract under this sec-
27 tion and to conduct appropriate education of and outreach
28 to such beneficiaries and monitoring quality of services with
29 respect to the program.

30 “(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

31 “(1) ESTABLISHMENT.—There is established a Pro-
32 gram Advisory and Oversight Committee (hereinafter in
33 this section referred to as the ‘Committee’).

34 “(2) MEMBERSHIP; TERMS.—The Committee shall
35 consist of such members as the Secretary may appoint who
36 shall serve for such term as the Secretary may specify.

37 “(3) DUTIES.—

1 “(A) TECHNICAL ASSISTANCE.—The Committee
2 shall provide advice and technical assistance to the Sec-
3 retary with respect to the following functions:

4 “(i) The implementation of the program under
5 this section.

6 “(ii) The establishment of requirements for
7 collection of data.

8 “(iii) The development of proposals for effi-
9 cient interaction among manufacturers and dis-
10 tributors of the items and services and providers
11 and beneficiaries.

12 “(B) ADDITIONAL DUTIES.—The Committee shall
13 perform such additional functions to assist the Sec-
14 retary in carrying out this section as the Secretary may
15 specify.

16 “(4) INAPPLICABILITY OF FACA.—The provisions of
17 the Federal Advisory Committee Act (5 U.S.C. App.) shall
18 not apply.

19 “(d) ANNUAL REPORTS.—The Secretary shall submit to
20 Congress an annual management report on the programs under
21 this section. Each such report shall include information on sav-
22 ings, reductions in beneficiary cost-sharing, access to and qual-
23 ity of items and services, and beneficiary satisfaction.

24 “(e) DEMONSTRATION PROJECT FOR CLINICAL LABORA-
25 TORY SERVICES.—

26 “(1) IN GENERAL.—The Secretary shall conduct a
27 demonstration project on the application of competitive ac-
28 quisition under this section to clinical diagnostic laboratory
29 tests—

30 “(A) for which payment is otherwise made under
31 section 1833(h) or 1834(d)(1) (relating to colorectal
32 cancer screening tests); and

33 “(B) which are furnished by entities that did not
34 have a face-to-face encounter with the individual.

35 “(2) TERMS AND CONDITIONS.—Such project shall be
36 under the same conditions as are applicable to items and
37 services described in subsection (a)(2).

1 “(3) REPORT.—The Secretary shall submit to
2 Congress—

3 “(A) an initial report on the project not later than
4 December 31, 2005; and

5 “(B) such progress and final reports on the
6 project after such date as the Secretary determines ap-
7 propriate.”.

8 (b) CONFORMING AMENDMENTS.—

9 (1) DURABLE MEDICAL EQUIPMENT; ELIMINATION OF
10 INHERENT REASONABLENESS AUTHORITY.—Section
11 1834(a) (42 U.S.C. 1395m(a)) is amended—

12 (A) in paragraph (1)(B), by striking “The pay-
13 ment basis” and inserting “Subject to subparagraph
14 (E)(i), the payment basis”;

15 (B) in paragraph (1)(C), by striking “This sub-
16 section” and inserting “Subject to subparagraph
17 (E)(ii), this subsection”;

18 (C) by adding at the end of paragraph (1) the fol-
19 lowing new subparagraph:

20 “(E) APPLICATION OF COMPETITIVE ACQUISITION;
21 ELIMINATION OF INHERENT REASONABLENESS AU-
22 THORITY.—In the case of covered items and services
23 that are included in a competitive acquisition program
24 in a competitive acquisition area under section
25 1847(a)—

26 “(i) the payment basis under this subsection
27 for such items and services furnished in such area
28 shall be the payment basis determined under such
29 competitive acquisition program; and

30 “(ii) the Secretary may use information on the
31 payment determined under such competitive acqui-
32 sition programs to adjust the payment amount oth-
33 erwise recognized under subparagraph (B)(ii) for
34 an area that is not a competitive acquisition area
35 under section 1847 and in the case of such adjust-
36 ment, paragraph (10)(B) shall not be applied.”;
37 and

(D) in paragraph (10)(B), by inserting “in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(E)” after “under this subsection”.

(2) OFF-THE-SHELF ORTHOTICS; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(h) (42 U.S.C. 1395m(h)) is amended—

(A) in paragraph (1)(B), by striking “and (E)” and inserting “, (E) , and (H)(i)”;

(B) in paragraph (1)(D), by striking “This subsection” and inserting “Subject to subparagraph (H)(ii), this subsection”;

(C) by adding at the end of paragraph (1) the following new subparagraph:

“(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(B) of section 1847(a) that are included in a competitive acquisition program in a competitive acquisition area under such section—

“(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

“(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.”.

(c) REPORT ON ACTIVITIES OF SUPPLIERS.—The Secretary shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program

1 under section 1847 of the Social Security Act, as amended by
2 subsection (a), are soliciting physicians to prescribe certain
3 brands or modes of delivery of covered items based on profit-
4 ability.

5 **SEC. 303. COMPETITIVE ACQUISITION OF COVERED**
6 **OUTPATIENT DRUGS AND BIOLOGICALS.**

7 (a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE.—

8 (1) ADJUSTMENT IN PRACTICE EXPENSE RELATIVE
9 VALUE UNITS.—Section 1848(c)(2) (42 U.S.C. 1395w-
10 4(c)(2)) is amended—

11 (A) in subparagraph (B)—

12 (i) in clause (ii)(II), by striking “The adjust-
13 ments” and inserting “Subject to clause (iv), the
14 adjustments”; and

15 (ii) by adding at the end of subparagraph (B),
16 the following new clause:

17 “(iv) EXCEPTION TO BUDGET NEUTRALITY.—
18 The additional expenditures attributable to clause
19 (ii) of subparagraph (H) shall not be taken into ac-
20 count in applying clause (ii)(II) for 2005.”; and

21 (B) by adding at the end the following new sub-
22 paragraph:

23 “(H) ADJUSTMENTS IN PRACTICE EXPENSE REL-
24 ATIVE VALUE UNITS FOR 2005.—

25 “(i) IN GENERAL.—As part of the annual
26 process of establishing the physician fee schedule
27 under subsection (b) for 2005, the Secretary shall
28 increase the practice expense relative value units
29 for 2005 consistent with clause (ii).

30 “(ii) USE OF SUPPLEMENTAL SURVEY DATA.—
31 For 2005 for any specialty that submitted survey
32 data that included expenses for the administration
33 of drugs and biologicals for which payment is made
34 under section 1842(o) (or section 1847A), the Sec-
35 retary shall use such supplemental survey data in
36 carrying out this subparagraph insofar as they are
37 collected and provided by entities and organizations

1 consistent with the criteria established by the Sec-
2 retary pursuant to section 212(a) of the Medicare,
3 Medicaid, and SCHIP Balanced Budget Refine-
4 ment Act of 1999 and insofar as such data are
5 submitted to the Secretary by December 31, 2004.

6 “(iii) SUBSEQUENT, BUDGET NEUTRAL AD-
7 JUSTMENTS PERMITTED.—Nothing in this subpara-
8 graph shall be construed as preventing the Sec-
9 retary from providing for adjustments in practice
10 expense relative value units under (and consistent
11 with) subparagraph (B) for years after 2005.

12 “(iv) CONSULTATION.—Before publishing the
13 notice of proposed rulemaking to carry out this
14 subparagraph, the Secretary shall consult with the
15 Comptroller General of the United States and with
16 groups representing the physician specialties in-
17 volved.

18 “(v) TREATMENT AS CHANGE IN LAW AND
19 REGULATION IN SUSTAINABLE GROWTH RATE DE-
20 TERMINATION.—The enactment of subparagraph
21 (B)(iv) and this subparagraph shall be treated as
22 a change in law for purposes of applying subsection
23 (f)(2)(D).”.

24 (2) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL
25 REVIEW.—Section 1848(i)(1) (42 U.S.C. 1395w-4(i)(1)) is
26 amended—

27 (A) by striking “and” at the end of subparagraph (D);
28 (B) by striking the period at the end of subparagraph
29 (E) and inserting “, and”; and
30 (C) by adding at the end the following new subpara-
31 graph:

32 “(F) adjustments in practice expense relative
33 value units for 2005 under subsection (c)(2)(H).”.

34 (3) TREATMENT OF OTHER SERVICES CURRENTLY IN
35 THE NON-PHYSICIAN WORK POOL.—The Secretary shall
36 make adjustments to the non-physician work pool method-
37 ology (as such term is used in the regulations promulgated

1 by the Secretary in the Federal Register as of December
2 31, 2002) for determination of practice expense relative
3 value units under the physician fee schedule described in
4 section 1848(c)(2)(C)(ii) of the Social Security Act so that
5 the practice expense relative value units for services deter-
6 mined under such methodology are not disproportionately
7 reduced relative to the practice expense relative value units
8 of other services not determined under such non-physician
9 work pool methodology, as the result of amendments made
10 by paragraph (1).

11 (b) PAYMENT BASED ON COMPETITION.—Title XVIII is
12 amended by inserting after section 1847 (42 U.S.C. 1395w-3),
13 as amended by section 302, the following new sections:

14 “COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS
15 AND BIOLOGICALS

16 “SEC. 1847A. (a) IMPLEMENTATION OF COMPETITIVE AC-
17 QUISITION.—

18 “(1) IMPLEMENTATION OF PROGRAM.—

19 “(A) IN GENERAL.—The Secretary shall establish
20 and implement a competitive acquisition program under
21 which—

22 “(i) competitive acquisition areas are estab-
23 lished throughout the United States for contract
24 award purposes for acquisition of and payment for
25 categories of covered outpatient drugs and
26 biologicals (as defined in paragraph (2)) under this
27 part;

28 “(ii) each physician is given the opportunity
29 annually to elect to obtain drugs and biologicals
30 under the program or under section 1847B; and

31 “(iii) each physician who elects to obtain drugs
32 and biologicals under the program makes an an-
33 nual selection under paragraph (5) of the con-
34 tractor through which drugs and biologicals within
35 a category of drugs and biologicals will be acquired
36 and delivered to the physician under this part.

1 “(B) IMPLEMENTATION.—The Secretary shall im-
2 plement the program so that the program applies to—

3 “(i) the oncology category beginning in 2005;
4 and

5 “(ii) the non-oncology category beginning in
6 2006.

7 This section shall not apply in the case of a physician
8 who elects section 1847B to apply.

9 “(C) EXCLUSION AUTHORITY.—The Secretary
10 may exclude covered outpatient drugs and biologicals
11 (including a class of such drugs and biologicals) from
12 the competitive bidding system under this section if the
13 drugs or biologicals (or class) are not appropriate for
14 competitive bidding due to low volume of utilization by
15 beneficiaries under this part or a unique mode or meth-
16 od of delivery.

17 “(2) COVERED OUTPATIENT DRUGS AND BIOLOGICALS,
18 CATEGORIES, PROGRAM DEFINED.—For purposes of this
19 section—

20 “(A) COVERED OUTPATIENT DRUGS AND
21 BIOLOGICALS DEFINED.—The term ‘covered outpatient
22 drugs and biologicals’ means drugs and biologicals to
23 which section 1842(o) applies and which are not cov-
24 ered under section 1847 (relating to competitive acqui-
25 sition for items of durable medical equipment). Such
26 term does not include the following:

27 “(i) Blood clotting factors.

28 “(ii) Drugs and biologicals furnished to indi-
29 viduals in connection with the treatment of end
30 stage renal disease.

31 “(iii) Radiopharmaceuticals.

32 “(B) 2 CATEGORIES.—Each of the following shall
33 be a separate category of covered outpatient drugs and
34 biologicals, as identified by the Secretary:

35 “(i) ONCOLOGY CATEGORY.—A category (in
36 this section referred to as the ‘oncology category’)
37 consisting of those covered outpatient drugs and

1 biologicals that, as determined by the Secretary,
2 are typically primarily billed by oncologists or are
3 otherwise used to treat cancer.

4 “(ii) NON-ONCOLOGY CATEGORIES.—Such
5 numbers of categories (in this section referred to as
6 the ‘non-oncology categories’) consisting of covered
7 outpatient drugs and biologicals not described in
8 clause (i), and appropriate subcategories of such
9 drugs and biologicals as the Secretary may specify.

10 “(C) PROGRAM.—The term ‘program’ means the
11 competitive acquisition program under this section.

12 “(D) COMPETITIVE ACQUISITION AREA; AREA.—
13 The terms ‘competitive acquisition area’ and ‘area’
14 mean an appropriate geographic region established by
15 the Secretary under the program.

16 “(E) CONTRACTOR.—The term ‘contractor’ means
17 an entity that has entered into a contract with the Sec-
18 retary under this section.

19 “(3) APPLICATION OF PROGRAM PAYMENT METHOD-
20 OLOGY.—With respect to covered outpatient drugs and
21 biologicals which are supplied under the program in an
22 area and which are prescribed by a physician who has not
23 elected section 1847B to apply—

24 “(A) the claim for such drugs and biologicals shall
25 be submitted by the contractor that supplied the drugs
26 and biologicals;

27 “(B) collection of amounts of any deductible and
28 coinsurance applicable with respect to such drugs and
29 biologicals shall be the responsibility of such contractor
30 and shall not be collected unless the drug or biological
31 is administered to the beneficiary involved; and

32 “(C) the payment under this section (and related
33 coinsurance amounts) for such drugs and biologicals—

34 “(i) shall be made only to such contractor;

35 “(ii) shall be conditioned upon the administra-
36 tion of such drugs and biologicals; and

1 “(iii) shall be based on the average of the bid
2 prices for such drugs and biologicals in the area, as
3 computed under subsection (d).

4 The Secretary shall provide a process for recoupment
5 in the case in which payment is made for drugs and
6 biologicals which were billed at the time of dispensing
7 but which were not actually administered.

8 “(4) CONTRACT REQUIRED.—

9 “(A) IN GENERAL.—Payment may not be made
10 under this part for covered outpatient drugs and
11 biologicals prescribed by a physician who has not elect-
12 ed section 1847B to apply within a category and a
13 competitive acquisition area with respect to which the
14 program applies unless—

15 “(i) the drugs or biologicals are supplied by a
16 contractor with a contract under this section for
17 such category of drugs and biologicals and area;
18 and

19 “(ii) the physician has elected such contractor
20 under paragraph (5) for such category and area.

21 “(B) PHYSICIAN CHOICE.—Subparagraph (A)
22 shall not apply for a category of drugs for an area if
23 the physician prescribing the covered outpatient drug
24 in such category and area has elected to apply section
25 1847B instead of this section.

26 “(5) CONTRACTOR SELECTION PROCESS.—

27 “(A) IN GENERAL.—The Secretary shall provide a
28 process for the selection of a contractor, on an annual
29 basis and in such exigent circumstances as the Sec-
30 retary may provide and with respect to each category
31 of covered outpatient drugs and biologicals for an area,
32 by physicians prescribing such drugs and biologicals in
33 the area of the contractor under this section that will
34 supply the drugs and biologicals within that category
35 and area. Such selection shall also include the election
36 described in section 1847B(a).

1 “(B) INFORMATION ON CONTRACTORS.—The Sec-
2 retary shall make available to physicians on an ongoing
3 basis, through a directory posted on the Department’s
4 Internet website or otherwise and upon request, a list
5 of the contractors under this section in the different
6 competitive acquisition areas.

7 “(C) SELECTING PHYSICIAN DEFINED.—For pur-
8 poses of this section, the term ‘selecting physician’
9 means, with respect to a contractor and category and
10 competitive acquisition area, a physician who has not
11 elected section 1847B to apply and has selected to
12 apply under this section such contractor for such cat-
13 egory and area.

14 “(b) PROGRAM REQUIREMENTS.—

15 “(1) CONTRACT FOR COVERED OUTPATIENT DRUGS
16 AND BIOLOGICALS.—The Secretary shall conduct a com-
17 petition among entities for the acquisition of a covered out-
18 patient drug or biological within each HCPCS code within
19 each category for each competitive acquisition area.

20 “(2) CONDITIONS FOR AWARDED CONTRACT.—

21 “(A) IN GENERAL.—The Secretary may not award
22 a contract to any entity under the competition con-
23 ducted in a competitive acquisition area pursuant to
24 paragraph (1) with respect to the acquisition of covered
25 outpatient drugs and biologicals within a category un-
26 less the Secretary finds that the entity meets all of the
27 following with respect to the contract period involved:

28 “(i) CAPACITY TO SUPPLY COVERED OUT-
29 PATIENT DRUG OR BIOLOGICAL WITHIN CAT-
30 EGORY.—

31 “(I) IN GENERAL.—The entity has suffi-
32 cient arrangements to acquire and to deliver
33 covered outpatient drugs and biologicals within
34 such category in the area specified in the con-
35 tract at the bid price specified in the contract
36 for all physicians that may elect such entity.

1 “(II) SHIPMENT METHODOLOGY.—The en-
2 tity has arrangements in effect for the ship-
3 ment at least 5 days each week of covered out-
4 patient drugs and biologicals under the con-
5 tract and for the timely delivery (including for
6 emergency situations) of such drugs and
7 biologicals in the area under the contract.

8 “(ii) QUALITY, SERVICE, FINANCIAL PERFORM-
9 ANCE AND SOLVENCY STANDARDS.—The entity
10 meets quality, service, financial performance, and
11 solvency standards specified by the Secretary,
12 including—

13 “(I) the establishment of procedures for
14 the prompt response and resolution of physi-
15 cian and beneficiary complaints and inquiries
16 regarding the shipment of covered outpatient
17 drugs and biologicals; and

18 “(II) a grievance process for the resolution
19 of disputes.

20 “(B) ADDITIONAL CONSIDERATIONS.—The Sec-
21 retary may refuse to award a contract under this sec-
22 tion, and may terminate such a contract, with an entity
23 based upon—

24 “(i) the suspension or revocation, by the Fed-
25 eral Government or a State government, of the en-
26 tity’s license for the distribution of drugs or
27 biologicals (including controlled substances); or

28 “(ii) the exclusion of the entity under section
29 1128 from participation under this title.

30 “(C) APPLICATION OF MEDICARE PROVIDER OM-
31 BUDSMAN.—For provision providing for a program-
32 wide Medicare Provider Ombudsman to review com-
33 plaints, see section 1868(b), as added by section 923
34 of the Medicare Prescription Drug and Modernization
35 Act of 2003.

36 “(3) AWARDING MULTIPLE CONTRACTS FOR A CAT-
37 EGORY AND AREA.—In order to provide a choice of at least

2 contractors in each competitive acquisition area for a category of drugs and biologicals, the Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

“(A) The bid prices for covered outpatient drugs and biologicals within the category and area.

“(B) Bid price for distribution of such drugs and biologicals.

“(C) Ability to ensure product integrity.

“(D) Customer service.

“(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

“(F) Such other factors as the Secretary may specify.

“(4) TERMS OF CONTRACTS.—

“(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

“(B) PERIOD OF CONTRACTS.—A contract under this section shall be for a term of 2 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

“(C) INTEGRITY OF DRUG AND BIOLOGICAL DISTRIBUTION SYSTEM.—The Secretary—

“(i) shall require that for all drug and biological products distributed by a contractor under this section be acquired directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

“(ii) may require, in the case of such products that are particularly susceptible to counterfeit or diversion, that the contractor comply with such additional product integrity safeguards as may be determined to be necessary.

1 “(D) IMPLEMENTATION OF ANTI-COUNTER-
2 FEITING, QUALITY, SAFETY, AND RECORD KEEPING RE-
3 QUIREMENTS.—The Secretary shall require each con-
4 tractor to implement (through its officers, agents, rep-
5 resentatives, and employees) requirements relating to
6 the storage and handling of covered outpatient drugs
7 and biologicals and for the establishment and mainte-
8 nance of distribution records for such drugs and
9 biologicals. A contract under this section may include
10 requirements relating to the following:

11 “(i) Secure facilities.

12 “(ii) Safe and appropriate storage of drugs
13 and biologicals.

14 “(iii) Examination of drugs and biologicals re-
15 ceived and dispensed.

16 “(iv) Disposition of damaged and outdated
17 drugs and biologicals.

18 “(v) Record keeping and written policies and
19 procedures.

20 “(vi) Compliance personnel.

21 “(E) COMPLIANCE WITH CODE OF CONDUCT AND
22 FRAUD AND ABUSE RULES.—Under the contract—

23 “(i) the contractor shall comply with a code of
24 conduct, specified or recognized by the Secretary,
25 that includes standards relating to conflicts of in-
26 terest; and

27 “(ii) the contractor shall comply with all appli-
28 cable provisions relating to prevention of fraud and
29 abuse, including compliance with applicable guide-
30 lines of the Department of Justice and the Inspec-
31 tor General of the Department of Health and
32 Human Services.

33 “(F) DIRECT DELIVERY OF DRUGS AND
34 BIOLOGICALS TO PHYSICIANS.—Under the contract the
35 contractor shall only supply covered outpatient drugs
36 and biologicals directly to the selecting physicians and
37 not directly to beneficiaries, except under circumstances

1 and settings where a beneficiary currently receives a
2 drug or biological in the beneficiary's home or other
3 non-physician office setting as the Secretary may pro-
4 vide. The contractor shall not deliver drugs and
5 biologicals to a selecting physician except upon receipt
6 of a prescription for such drugs and biologicals, and
7 such necessary data as may be required by the Sec-
8 retary to carry out this section. This section permits a
9 physician to submit a prescription for each individual
10 treatment but does not change the physician's flexi-
11 bility in terms of writing a prescription for drugs for
12 a single treatment or a course of treatment.

13 “(5) PERMITTING ACCESS TO DRUGS AND
14 BIOLOGICALS.—The Secretary shall provide for the reim-
15 bursement at the average sales price under section 1847B
16 for drugs and biologicals if the physician demonstrates all
17 of the following:

18 “(A) The drugs or biologicals are immediately re-
19 quired.

20 “(B) The physician could not have reasonably an-
21 ticipated the immediate requirement for the drugs or
22 biologicals.

23 “(C) The contractor could not deliver to the physi-
24 cian the drugs or biologicals in a timely manner.

25 “(6) CONSTRUCTION.—Nothing in this section shall be
26 construed as waiving applicable State requirements relating
27 to licensing of pharmacies.

28 “(c) BIDDING PROCESS.—

29 “(1) IN GENERAL.—In awarding a contract for a cat-
30 egory of drugs and biologicals in an area under the pro-
31 gram, the Secretary shall consider with respect to each en-
32 tity seeking to be awarded a contract the prices bid to ac-
33 quire and supply the covered outpatient drugs and
34 biologicals for that category and area and the other factors
35 referred to in subsection (b)(3).

36 “(2) PRICES BID.—The prices bid by an entity under
37 paragraph (1) shall be the prices in effect and available for

1 the supply of contracted drugs and biologicals in the area
2 through the entity for the contract period.

3 “(3) REJECTION OF CONTRACT OFFER.—The Sec-
4 retary shall reject the contract offer of an entity with re-
5 spect to a category of drugs and biologicals for an area if
6 the Secretary estimates that the prices bid, in the aggre-
7 gate on average, would exceed 120 percent of the average
8 sales price (as determinend under section 1847B).

9 “(4) BIDDING ON A NATIONAL OR REGIONAL BASIS.—
10 Nothing in this section shall be construed as precluding a
11 bidder from bidding for contracts in all areas of the United
12 States or as requiring a bidder to submit a bid for all areas
13 of the United States.

14 “(5) UNIFORMITY OF BIDS WITHIN AREA.—The
15 amount of the bid submitted under a contract offer for any
16 covered outpatient drug or biological for an area shall be
17 the same for that drug or biological for all portions of that
18 area.

19 “(6) CONFIDENTIALITY OF BIDS.—The provisions of
20 subparagraph (D) of section 1927(b)(3) shall apply to a bid
21 submitted in a contract offer for a covered outpatient drug
22 or biological under this section in the same manner as it
23 applies to information disclosed under such section, except
24 that any reference—

25 “(A) in that subparagraph to a ‘manufacturer or
26 wholesaler’ is deemed a reference to a ‘bidder’ under
27 this section;

28 “(B) in that section to ‘prices charged for drugs’
29 is deemed a reference to a ‘bid’ submitted under this
30 section; and

31 “(C) in clause (i) of that section to ‘this section’,
32 is deemed a reference to ‘part B of title XVIII’.

33 “(7) INCLUSION OF COSTS.—The bid price submitted
34 in a contract offer for a covered outpatient drug or biologi-
35 cal shall—

1 “(A) include all costs related to the delivery of the
2 drug or biological to the selecting physician (or other
3 point of delivery); and

4 “(B) include the costs of dispensing (including
5 shipping) of such drug or biological and management
6 fees, but shall not include any costs related to the ad-
7 ministration of the drug or biological, or wastage, spill-
8 age, or spoilage.

9 “(8) PRICE ADJUSTMENTS DURING CONTRACT PERIOD;
10 DISCLOSURE OF COSTS.—Each contract awarded shall pro-
11 vide for—

12 “(A) disclosure to the Secretary the contractor’s
13 reasonable, net acquisition costs for periods specified by
14 the Secretary, not more often than quarterly, of the
15 contract; and

16 “(B) appropriate price adjustments over the pe-
17 riod of the contract to reflect significant increases or
18 decreases in a contractor’s reasonable, net acquisition
19 costs, as so disclosed.

20 “(d) COMPUTATION OF AVERAGE BID PRICES FOR A CAT-
21 EGORY AND AREA.—

22 “(1) IN GENERAL.—For each year or other contract
23 period for each covered outpatient drug or biological and
24 area with respect to which a competition is conducted
25 under the program, the Secretary shall compute an area
26 average of the bid prices submitted, in contract offers ac-
27 cepted for the category and area, for that year or other
28 contract period.

29 “(2) SPECIAL RULES.—The Secretary shall establish
30 rules regarding the use under this section of the alternative
31 payment amount provided under section 1847B to the use
32 of a price for specific covered outpatient drugs and
33 biologicals in the following cases:

34 “(A) NEW DRUGS AND BIOLOGICALS.—A covered
35 outpatient drug or biological for which an average bid
36 price has not been previously determined.

1 “(B) OTHER CASES.—Such other exceptional cases
2 as the Secretary may specify in regulations.

3 “(C) EXCLUSION CASES.—A covered outpatient
4 drug or biological that has been excluded under sub-
5 section (a)(1)(C).

6 Such alternative payment amount shall be based upon ac-
7 tual market price information and in no case shall it exceed
8 the average sales price (as determined under section
9 1847B).

10 “(e) COINSURANCE.—

11 “(1) IN GENERAL.—Coinsurance under this part with
12 respect to a covered outpatient drug or biological for which
13 payment is payable under this section shall be based on 20
14 percent of the payment basis under this section.

15 “(2) COLLECTION.—Such coinsurance shall be col-
16 lected by the contractor that supplies the drug or biological
17 involved and, subject to subsection (a)(3)(B), in the same
18 manner as coinsurance is collected for durable medical
19 equipment under this part.

20 “(f) SPECIAL PAYMENT RULES.—

21 “(1) IN GENERAL.—The Secretary may not provide
22 for an adjustment to reimbursement for covered outpatient
23 drugs and biologicals unless adjustments to the practice ex-
24 pense payment adjustment are made on the basis of supple-
25 mental surveys under section 1848(c)(2)(H)(ii) of the So-
26 cial Security Act, as added by subsection (a)(1)(B).

27 “(B) USE IN EXCLUSION CASES.—If the Secretary
28 excludes a drug or biological (or class of drugs or
29 biologicals) under subsection (a)(1)(D), the Secretary
30 may provide for reimbursement to be made under this
31 part for such drugs and biologicals (or class) using the
32 payment methodology under section 1847B or other
33 market based pricing system.

34 “(2) COORDINATION RULES.—The provisions of sec-
35 tion 1842(h)(3) shall apply to a contractor with respect to
36 covered outpatients drugs and biologicals supplied by that
37 contractor in the same manner as they apply to a partici-

1 pating supplier. In order to administer this section, the
2 Secretary may condition payment under this part to a per-
3 son for the administration of a drug or biological supplied
4 under this section upon person's provision of information
5 on such administration.

6 “(3) APPLICATION OF REQUIREMENT FOR ASSIGN-
7 MENT.—For provision requiring assignment of claims for
8 covered outpatient drugs and biologicals, see section
9 1842(o)(3).

10 “(4) PROTECTION FOR BENEFICIARY IN CASE OF MED-
11 ICAL NECESSITY DENIAL.—For protection of beneficiaries
12 against liability in the case of medical necessity determina-
13 tions, see section 1842(b)(3)(B)(ii)(III).

14 “(5) PHYSICIAN ROLE IN APPEALS PROCESS.—The
15 Secretary shall establish a procedure under which a physi-
16 cian who prescribes a drug or biological for which payment
17 is made under this section has appeal rights that are simi-
18 lar to those provided to a physician who prescribes durable
19 medical equipment or a laboratory test.

20 “(g) ADVISORY COMMITTEE.—The Secretary shall estab-
21 lish an advisory committee that includes representatives of par-
22 ties affected by the program under this section, including phy-
23 sicians, specialty pharmacies, distributors, manufacturers, and
24 beneficiaries. The committee shall advise the Secretary on
25 issues relating to the effective implementation of this section.

26 “OPTIONAL USE OF AVERAGE SALES PRICE PAYMENT
27 METHODOLOGY

28 “SEC. 1847B. (a) ELECTION AND IMPLEMENTATION.—

29 “(1) ELECTION.—In connection with the annual elec-
30 tion made by a physician under section 1847A(a)(5), the
31 physician may elect to apply this section to the payment for
32 covered outpatient drugs and biologicals instead of the pay-
33 ment methodology under section 1847A.

34 “(2) IMPLEMENTATION.—This section shall be imple-
35 mented with respect to categories of covered outpatient

36 “(3) COVERED OUTPATIENT DRUGS AND BIOLOGICALS
37 DEFINED.—For purposes of this section, the term ‘covered

1 outpatient drugs and biologicals' has the meaning given
2 such term in section 1847A(a)(2)(A).

3 “(b) COMPUTATION OF PAYMENT AMOUNT.—

4 “(1) IN GENERAL.—If this section applies with respect
5 to a covered outpatient drug or biological, the amount pay-
6 able for the drug or biological (based on a minimum dosage
7 unit) is, subject to applicable deductible and coinsurance—

8 “(A) in the case of a multiple source drug (as de-
9 fined in subsection (c)(6)(C)), the amount determined
10 under paragraph (3); or

11 “(B) in the case of a single source drug (as de-
12 fined in subsection (c)(6)(D)), the amount determined
13 under paragraph (4).

14 “(2) SPECIFICATION OF UNIT.—

15 “(A) SPECIFICATION BY MANUFACTURER.—The
16 manufacturer of a covered outpatient drug or biological
17 shall specify the unit associated with each National
18 Drug Code as part of the submission of data under sec-
19 tion 1927(b)(3)(A)(iii).

20 “(B) UNIT DEFINED.—In this section, the term
21 ‘unit’ means, with respect to a covered outpatient drug
22 or biological, the lowest identifiable quantity (such as
23 a capsule or tablet, milligram of molecules, or grams)
24 of the drug or biological that is dispensed, exclusive of
25 any diluent without reference to volume measures per-
26 taining to liquids.

27 “(3) MULTIPLE SOURCE DRUG.—For all drug prod-
28 ucts included within the same multiple source drug, the
29 amount specified in this paragraph is the volume-weighted
30 average of the average sales prices reported under section
31 1927(b)(3)(A)(iii) computed as follows:

32 “(A) Compute the sum of the products (for each
33 national drug code assigned to such drug products)
34 of—

35 “(i) the manufacturer’s average sales price (as
36 defined in subsection (c)); and

1 “(ii) the total number of units specified under
2 paragraph (2) sold, as reported under section
3 1927(b)(3)(A)(iii).

4 “(B) Divide the sum computed under subpara-
5 graph (A) by the sum of the total number of units
6 under subparagraph (A)(ii) for all national drug codes
7 assigned to such drug products.

8 “(4) SINGLE SOURCE DRUG.—The amount specified in
9 this paragraph for a single source drug is the lesser of the
10 following:

11 “(A) MANUFACTURER’S AVERAGE SALES PRICE.—
12 The manufacturer’s average sales price for a national
13 drug code, as computed using the methodology applied
14 under paragraph (3).

15 “(B) WHOLESALE ACQUISITION COST (WAC).—The
16 wholesale acquisition cost (as defined in subsection
17 (c)(6)(B)) reported for the single source drug.

18 “(5) BASIS FOR DETERMINATION.—The payment
19 amount shall be determined under this subsection based on
20 information reported under subsection (e) and without re-
21 gard to any special packaging, labeling, or identifiers on
22 the dosage form or product or package.

23 “(c) MANUFACTURER’S AVERAGE SALES PRICE.—

24 “(1) IN GENERAL.—For purposes of this subsection,
25 subject to paragraphs (2) and (3), the manufacturer’s ‘av-
26 erage sales price’ means, of a covered outpatient drug or
27 biological for a NDC code for a calendar quarter for a
28 manufacturer for a unit—

29 “(A) the manufacturer’s total sales (as defined by
30 the Secretary in regulations for purposes of section
31 1927(c)(1)) in the United States for such drug or bio-
32 logical in the calendar quarter; divided by

33 “(B) the total number of such units of such drug
34 or biological sold by the manufacturer in such quarter.

35 “(2) CERTAIN SALES EXEMPTED FROM COMPUTA-
36 TION.—In calculating the manufacturer’s average sales

1 price under this subsection, the following sales shall be ex-
2 cluded:

3 “(A) SALES EXEMPT FROM BEST PRICE.—Sales
4 exempt from the inclusion in the determination of ‘best
5 price’ under section 1927(c)(1)(C)(i).

6 “(B) SALES AT NOMINAL CHARGE.—Such other
7 sales as the Secretary identifies by regulation as sales
8 to an entity that are nominal in price or do not reflect
9 a market price paid by an entity to which payment is
10 made under this section.

11 “(3) SALE PRICE NET OF DISCOUNTS.—In calculating
12 the manufacturer’s average sales price under this sub-
13 section, such price shall be determined taking into account
14 volume discounts, prompt pay discounts, cash discounts,
15 the free goods that are contingent on any purchase require-
16 ment, chargebacks, and rebates (other than rebates under
17 section 1927), that result in a reduction of the cost to the
18 purchaser. A rebate to a payor or other entity that does not
19 take title to a covered outpatient drug or biological shall
20 not be taken into account in determining such price unless
21 the manufacturer has an agreement with the payor or other
22 entity under which the purchaser’s price for the drug or bi-
23 ological is reduced as a consequence of such rebate.

24 “(4) AUTHORITY TO DISREGARD AVERAGE SALES
25 PRICE DURING FIRST QUARTER OF SALES.—In the case of
26 a covered outpatient drug or biological during an initial pe-
27 riod (not to exceed a full calendar quarter) in which data
28 on the prices for sales for the drug or biological is not
29 available from the manufacturer to compute an average
30 sales price for the drug or biological, the Secretary may de-
31 termine the amount payable under this section for the drug
32 or biological without considering the manufacturer’s aver-
33 age sales price of that manufacturer for that drug or bio-
34 logical.

35 “(5) FREQUENCY OF DETERMINATIONS.—

36 “(A) IN GENERAL ON A QUARTERLY BASIS.—The
37 manufacturer’s average sales price, for a covered out-

1 patient drug or biological of a manufacturer, shall be
2 determined by such manufacturer under this subsection
3 on a quarterly basis. In making such determination in-
4 sofar as there is a lag in the reporting of the informa-
5 tion on rebates and chargebacks under paragraph (3)
6 so that adequate data are not available on a timely
7 basis, the manufacturer shall apply a methodology es-
8 tablished by the Secretary based on a 12-month rolling
9 average for the manufacturer to estimate costs attrib-
10 utable to rebates and chargebacks.

11 “(B) UPDATES IN RATES.—The payment rates
12 under subsection (b)(1) and (b)(2)(A) shall be updated
13 by the Secretary on a quarterly basis and shall be ap-
14 plied based upon the manufacturer’s average sales price
15 determined for the most recent calendar quarter.

16 “(C) USE OF CONTRACTORS; IMPLEMENTATION.—
17 The Secretary may use a carrier, fiscal intermediary, or
18 other contractor to determine the payment amount
19 under subsection (b). Notwithstanding any other provi-
20 sion of law, the Secretary may implement, by program
21 memorandum or otherwise, any of the provisions of this
22 section.

23 “(6) DEFINITIONS AND OTHER RULES.—In this sec-
24 tion:

25 “(A) MANUFACTURER.—The term ‘manufacturer’
26 means, with respect to a covered outpatient drug or bi-
27 ological, the manufacturer (as defined in section
28 1927(k)(5)) whose national drug code appears on such
29 drug or biological.

30 “(ii) WHOLESAL ACQUISITION COST.—The term
31 ‘wholesale acquisition cost’ means, with respect to a
32 covered outpatient drug or biological, the manufactur-
33 er’s list price for the drug or biological to wholesalers
34 or direct purchasers in the United States, not including
35 prompt pay or other discounts, rebates or reductions in
36 price, for the most recent month for which the informa-

tion is available, as reported in wholesale price guides or other publications of drug pricing data.

“(C) MULTIPLE SOURCE DRUG.—The term ‘multiple source drug’ means, for a calendar quarter, a covered outpatient drug or biological for which there are 2 or more drug products which—

“(i) are rated as therapeutically equivalent (under the Food and Drug Administration’s most recent publication of ‘Approved Drug Products with Therapeutic Equivalence Evaluations’),

“(ii) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

“(iii) are sold or marketed in the United States during the quarter.

“(D) SINGLE SOURCE DRUG.—The term ‘single source drug’ means a covered outpatient drug or biological which is not a multiple source drug and which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application, or which is a biological.

“(E) EXCEPTION FROM PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

“(F) DETERMINATION OF PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE.—For purposes of this paragraph—

1 “(i) drug products are pharmaceutically equiv-
2 alent if the products contain identical amounts of
3 the same active drug ingredient in the same dosage
4 form and meet compendial or other applicable
5 standards of strength, quality, purity, and identity;
6 and

7 “(ii) drugs are bioequivalent if they do not
8 present a known or potential bioequivalence prob-
9 lem, or, if they do present such a problem, they are
10 shown to meet an appropriate standard of bio-
11 equivalence.

12 “(G) INCLUSION OF VACCINES.—In applying pro-
13 visions of section 1927 under this section, ‘other than
14 a vaccine’ is deemed deleted from section
15 1927(k)(2)(B).

16 “(d) AUTHORITY TO USE ALTERNATIVE PAYMENT IN RE-
17 SPONSE TO PUBLIC HEALTH EMERGENCY.—In the case of a
18 public health emergency under section 319 of the Public Health
19 Service Act in which there is a documented inability to access
20 covered outpatient drugs and biologicals, and a concomitant in-
21 crease in the price, of a drug or biological which is not reflected
22 in the manufacturer’s average sales price for one or more quar-
23 ters, the Secretary may use the wholesale acquisition cost (or
24 other reasonable measure of drug price) instead of the manu-
25 facturer’s average sales price for such quarters and for subse-
26 quent quarters until the price and availability of the drug or
27 biological has stabilized and is substantially reflected in the ap-
28 plicable manufacturer’s average sales price.

29 “(e) REPORTS.—

30 “(1) QUARTERLY REPORT ON AVERAGE SALES
31 PRICE.—For requirements for reporting the manufacturer’s
32 average sales price (and, if required to make payment, the
33 manufacturer’s wholesale acquisition cost) for the covered
34 outpatient drug or biological, see section 1927(b)(3).

35 “(2) ANNUAL REPORT TO CONGRESS.—The Secretary
36 shall submit to the Committees on Energy and Commerce
37 and Ways and Means of the House of Representatives and

1 the Committee on Finance of the Senate an annual report
2 on the operation of this section and section 1847A. Such
3 report shall include information on the following:

4 “(A) Information on savings, reductions in cost-
5 sharing, access to covered outpatient drugs and
6 biologicals.

7 “(B) In the case of section 1847A, the range of
8 choices of contractors available to providers, and bene-
9 ficiary and provider satisfaction.

10 “(C) Trends in average sales price under sub-
11 section (b).

12 “(D) Administrative costs associated with compli-
13 ance with this section.

14 “(E) Total value of payments made under this sec-
15 tion.

16 “(F) Comparison of the average manufacturer
17 price as applied under section 1927 for a covered out-
18 patient drug or biological with the manufacturer’s aver-
19 age sales price for the drug or biological under this sec-
20 tion.

21 “(f) RESTRICTION ON ADMINISTRATIVE AND JUDICIAL RE-
22 VIEW.—There shall be no administrative or judicial review
23 under section 1869, section 1878, or otherwise, of determina-
24 tions of manufacturer’s average sales price under subsection
25 (c).”.

26 (c) CONTINUATION OF PAYMENT METHODOLOGY FOR
27 RADIOPHARMACEUTICALS.—Nothing in the amendments made
28 by this section shall be construed as changing the payment
29 methodology under part B of title XVIII of the Social Security
30 Act for radiopharmaceuticals, including the use by carriers of
31 invoice pricing methodology.

32 (d) CONFORMING AMENDMENTS.—

33 (1) IN GENERAL.—Section 1842(o) (42 U.S.C.
34 1395u(o)) is amended—

35 (A) in paragraph (1), by inserting “, subject to
36 section 1847A and 1847B,” before “the amount pay-
37 able for the drug or biological”; and

1 (B) by adding at the end of paragraph (2) the fol-
2 lowing: “This paragraph shall not apply in the case of
3 payment under section 1847A or 1847B.”.

4 (2) NO CHANGE IN COVERAGE BASIS.—Section
5 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by
6 inserting “(or would have been so included but for the ap-
7 plication of section 1847A or 1847B)” after “included in
8 the physicians’ bills”.

9 (3) PAYMENT.—Section 1833(a)(1)(S) (42 U.S.C.
10 1395l(a)(1)(S)) is amended by inserting “(or, if applicable,
11 under section 1847A or 1847B)” after “1842(o)”.

12 (4) CONSOLIDATED REPORTING OF PRICING INFORMA-
13 TION.—Section 1927 (42 U.S.C. 1396r-8) is amended—

14 (A) in subsection (a)(1), by inserting “or under
15 part B of title XVIII” after “section 1903(a)”;

16 (B) in subsection (b)(3)(A)—

17 (i) in clause (i), by striking “and” at the end;

18 (ii) in clause (ii), by striking the period and
19 inserting “; and”; and

20 (iii) by adding at the end the following new
21 clause:

22 “(iii) for calendar quarters beginning on or
23 after April 1, 2004, in conjunction with reporting
24 required under clause (i) and by national drug code
25 (NDC)—

26 “(I) the manufacturer’s average sales
27 price (as defined in section 1847B(c)) and the
28 total number of units specified under section
29 1847B(b)(2)(A);

30 “(II) if required to make payment under
31 section 1847B, the manufacturer’s wholesale
32 acquisition cost, as defined in subsection (c)(6)
33 of such section; and

34 “(III) information on those sales that were
35 made at a nominal price or otherwise described
36 in section 1847B(c)(2)(B), which information
37 is subject to audit by the Inspector General of

1 the Department of Health and Human Serv-
2 ices;

3 for a covered outpatient drug or biological for
4 which payment is made under section 1847B.”;

5 (C) in subsection (b)(3)(B)—

6 (i) in the heading, by inserting “AND MANU-
7 FACTURER’S AVERAGE SALES PRICE” after
8 “PRICE”; and

9 (ii) by inserting “and manufacturer’s average
10 sales prices (including wholesale acquisition cost) if
11 required to make payment” after “manufacturer
12 prices”; and

13 (D) in subsection (b)(3)(D)(i), by inserting “and
14 section 1847B” after “this section”.

15 (e) GAO STUDY.—

16 (1) STUDY.—The Comptroller General of the United
17 States shall conduct a study to assess the impact of the
18 amendments made by this section on the delivery of serv-
19 ices, including their impact on—

20 (A) beneficiary access to drugs and biologicals for
21 which payment is made under part B of title XVIII of
22 the Social Security Act; and

23 (B) the site of delivery of such services.

24 (2) REPORT.—Not later than 2 years after the year in
25 which the amendment made by subsection (a)(1) first takes
26 effect, the Comptroller General shall submit to Congress a
27 report on the study conducted under paragraph (1).

28 (f) MEDPAC RECOMMENDATIONS ON BLOOD CLOTTING
29 FACTORS.—The Medicare Payment Advisory Commission shall
30 submit to Congress, in its annual report in 2004, specific rec-
31 ommendations regarding a payment amount (or amounts) for
32 blood clotting factors and its administration under the medi-
33 care program.

34 (g) ESTABLISHMENT OF PHARMACEUTICAL MANAGEMENT
35 FEE WHERE DRUGS PROVIDED THROUGH A CONTRACTOR.—
36 Section 1848(a) (42 U.S.C. 1395w-4(a)) is amended by adding
37 at the end the following new paragraph:

1 “(5) RECOGNITION OF PHARMACEUTICAL MANAGE-
2 MENT FEE IN CERTAIN CASES.—In establishing the fee
3 schedule under this section, the Secretary shall provide for
4 a separate payment with respect to physicians’ services con-
5 sisting of the unique administrative and management costs
6 associated with covered drugs and biologicals which are fur-
7 nished to physicians through a contractor under section
8 1847A (compared with such costs if such drugs and
9 biologicals were acquired directly by such physicians).”.

10 (h) STUDY ON CODES FOR NON-ONCOLOGY CODES.—

11 (1) STUDY.—The Secretary shall conduct a study to
12 determine the appropriateness of establishing and imple-
13 menting separate CPT codes for non-oncology infusions
14 that are based on the level of complexity of the administra-
15 tion and resource consumption.

16 (2) REPORT.—Not later than 1 year after the date of
17 the enactment of this Act, the Secretary shall submit a re-
18 port to Congress on the study. To the extent the Secretary
19 determines it to be appropriate, the Secretary may imple-
20 ment appropriate changes in the payment methodology for
21 such codes.

22 **SEC. 304. DEMONSTRATION PROJECT FOR USE OF RE-**
23 **COVERY AUDIT CONTRACTORS.**

24 (a) IN GENERAL.—The Secretary of Health and Human
25 Services shall conduct a demonstration project under this sec-
26 tion (in this section referred to as the “project”) to dem-
27 onstrate the use of recovery audit contractors under the Medi-
28 care Integrity Program in identifying underpayments and over-
29 payments and recouping overpayments under the medicare pro-
30 gram for services for which payment is made under part A or
31 part B of title XVIII of the Social Security Act. Under the
32 project—

33 (1) payment may be made to such a contractor on a
34 contingent basis;

35 (2) a percentage of the amount recovered may be re-
36 tained by the Secretary and shall be available to the pro-

1 gram management account of the Centers for Medicare &
2 Medicaid Services; and

3 (3) the Secretary shall examine the efficacy of such
4 use with respect to duplicative payments, accuracy of cod-
5 ing, and other payment policies in which inaccurate pay-
6 ments arise.

7 (b) SCOPE AND DURATION.—

8 (1) SCOPE.—The project shall cover at least 2 States
9 that are among the States with—

10 (A) the highest per capita utilization rates of
11 medicare services, and

12 (B) at least 3 contractors.

13 (2) DURATION.—The project shall last for not longer
14 than 3 years.

15 (c) WAIVER.—The Secretary of Health and Human Serv-
16 ices shall waive such provisions of title XVIII of the Social Se-
17 curity Act as may be necessary to provide for payment for serv-
18 ices under the project in accordance with subsection (a).

19 (d) QUALIFICATIONS OF CONTRACTORS.—

20 (1) IN GENERAL.—The Secretary shall enter into a re-
21 covery audit contract under this section with an entity only
22 if the entity has staff that has the appropriate clinical
23 knowledge of and experience with the payment rules and
24 regulations under the medicare program or the entity has
25 or will contract with another entity that has such knowl-
26 edgeable and experienced staff.

27 (2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The
28 Secretary may not enter into a recovery audit contract
29 under this section with an entity to the extent that the en-
30 tity is a fiscal intermediary under section 1816 of the So-
31 cial Security Act (42 U.S.C. 1395h), a carrier under sec-
32 tion 1842 of such Act (42 U.S.C. 1395u), or a Medicare
33 Administrative Contractor under section 1874A of such
34 Act.

35 (3) PREFERENCE FOR ENTITIES WITH DEM-
36 ONSTRATED PROFICIENCY WITH PRIVATE INSURERS.—In
37 awarding contracts to recovery audit contractors under this

1 section, the Secretary shall give preference to those risk en-
2 tities that the Secretary determines have demonstrated
3 more than 3 years direct management experience and a
4 proficiency in recovery audits with private insurers or
5 under the medicaid program under title XIX of such Act.

6 (e) CONSTRUCTION RELATING TO CONDUCT OF INVES-
7 TIGATION OF FRAUD.—A recovery of an overpayment to a pro-
8 vider by a recovery audit contractor shall not be construed to
9 prohibit the Secretary or the Attorney General from inves-
10 tigating and prosecuting, if appropriate, allegations of fraud or
11 abuse arising from such overpayment.

12 (f) REPORT.—The Secretary of Health and Human Serv-
13 ices shall submit to Congress a report on the project not later
14 than 6 months after the date of its completion. Such reports
15 shall include information on the impact of the project on sav-
16 ings to the medicare program and recommendations on the
17 cost-effectiveness of extending or expanding the project.

18 **TITLE IV—RURAL HEALTH CARE** 19 **IMPROVEMENTS**

20 **SEC. 401. ENHANCED DISPROPORTIONATE SHARE HOS-** 21 **PITAL (DSH) TREATMENT FOR RURAL HOS-** 22 **PITALS AND URBAN HOSPITALS WITH** 23 **FEWER THAN 100 BEDS.**

24 (a) DOUBLING THE CAP.—

25 (1) IN GENERAL.—Section 1886(d)(5)(F) (42 U.S.C.
26 1395ww(d)(5)(F)) is amended by adding at the end the fol-
27 lowing new clause:

28 “(xiv)(I) In the case of discharges in a fiscal year begin-
29 ning on or after October 1, 2003, subject to subclause (II),
30 there shall be substituted for the disproportionate share adjust-
31 ment percentage otherwise determined under clause (iv) (other
32 than subclause (I)) or under clause (viii), (x), (xi), (xii), or
33 (xiii), the disproportionate share adjustment percentage deter-
34 mined under clause (vii) (relating to large, urban hospitals).

35 “(II) Under subclause (I), the disproportionate share ad-
36 justment percentage shall not exceed 10 percent for a hospital

1 that is not classified as a rural referral center under subpara-
2 graph (C).”.

3 (2) CONFORMING AMENDMENTS.—Section
4 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

5 (A) in each of subclauses (II), (III), (IV), (V), and
6 (VI) of clause (iv), by inserting “subject to clause (xiv)
7 and” before “for discharges occurring”;

8 (B) in clause (viii), by striking “The formula” and
9 inserting “Subject to clause (xiv), the formula”; and

10 (C) in each of clauses (x), (xi), (xii), and (xiii), by
11 striking “For purposes” and inserting “Subject to
12 clause (xiv), for purposes”.

13 (b) EFFECTIVE DATE.—The amendments made by this
14 section shall apply with respect to discharges occurring on or
15 after October 1, 2003.

16 **SEC. 402. IMMEDIATE ESTABLISHMENT OF UNIFORM**
17 **STANDARDIZED AMOUNT IN RURAL AND**
18 **SMALL URBAN AREAS.**

19 (a) IN GENERAL.—Section 1886(d)(3)(A) (42 U.S.C.
20 1395ww(d)(3)(A)) is amended—

21 (1) in clause (iv), by inserting “and ending on or be-
22 fore September 30, 2003,” after “October 1, 1995,”; and

23 (2) by redesignating clauses (v) and (vi) as clauses
24 (vii) and (viii), respectively, and inserting after clause (iv)
25 the following new clauses:

26 “(v) For discharges occurring in the fiscal year begin-
27 ning on October 1, 2003, the average standardized amount
28 for hospitals located in areas other than a large urban area
29 shall be equal to the average standardized amount for hos-
30 pitals located in a large urban area.”.

31 (b) CONFORMING AMENDMENTS.—

32 (1) COMPUTING DRG-SPECIFIC RATES.—Section
33 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

34 (A) in the heading, by striking “IN DIFFERENT
35 AREAS”;

36 (B) in the matter preceding clause (i), by striking
37 “, each of”;

1 (C) in clause (i)—

2 (i) in the matter preceding subclause (I), by
3 inserting “for fiscal years before fiscal year 2004,”
4 before “for hospitals”; and

5 (ii) in subclause (II), by striking “and” after
6 the semicolon at the end;

7 (D) in clause (ii)—

8 (i) in the matter preceding subclause (I), by
9 inserting “for fiscal years before fiscal year 2004,”
10 before “for hospitals”; and

11 (ii) in subclause (II), by striking the period at
12 the end and inserting “; and”; and

13 (E) by adding at the end the following new clause:

14 “(iii) for a fiscal year beginning after fiscal year
15 2003, for hospitals located in all areas, to the product
16 of—

17 “(I) the applicable standardized amount (com-
18 puted under subparagraph (A)), reduced under
19 subparagraph (B), and adjusted or reduced under
20 subparagraph (C) for the fiscal year; and

21 “(II) the weighting factor (determined under
22 paragraph (4)(B)) for that diagnosis-related
23 group.”.

24 (2) TECHNICAL CONFORMING SUNSET.—Section
25 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

26 (A) in the matter preceding subparagraph (A), by
27 inserting “, for fiscal years before fiscal year 1997,”
28 before “a regional adjusted DRG prospective payment
29 rate”; and

30 (B) in subparagraph (D), in the matter preceding
31 clause (i), by inserting “, for fiscal years before fiscal
32 year 1997,” before “a regional DRG prospective pay-
33 ment rate for each region,”.

34 **SEC. 403. ESTABLISHMENT OF ESSENTIAL RURAL HOS-**
35 **PITAL CLASSIFICATION.**

36 (a) CLASSIFICATION.—Section 1861(mm) (42 U.S.C.
37 1395x(mm)) is amended—

1 (1) in the heading by adding “ESSENTIAL RURAL
2 HOSPITALS” at the end; and

3 (2) by adding at the end the following new para-
4 graphs:

5 “(4)(A) The term ‘essential rural hospital’ means a sub-
6 section (d) hospital (as defined in section 1886(d)(1)(B)) that
7 is located in a rural area (as defined for purposes of section
8 1886(d)), has more than 25 licensed acute care inpatient beds,
9 has applied to the Secretary for classification as such a hos-
10 pital, and with respect to which the Secretary has determined
11 that the closure of the hospital would significantly diminish the
12 ability of medicare beneficiaries to obtain essential health care
13 services.

14 “(B) The determination under subparagraph (A) shall be
15 based on the following criteria:

16 “(i) HIGH PROPORTION OF MEDICARE BENEFICIARIES
17 RECEIVING CARE FROM HOSPITAL.—(I) A high percentage
18 of such beneficiaries residing in the area of the hospital
19 who are hospitalized (during the most recent year for which
20 complete data are available) receive basic inpatient medical
21 care at the hospital.

22 “(II) For a hospital with more than 200 licensed beds,
23 a high percentage of such beneficiaries residing in such
24 area who are hospitalized (during such recent year) receive
25 specialized surgical inpatient care at the hospital.

26 “(III) Almost all physicians described in section
27 1861(r)(1) in such area have privileges at the hospital and
28 provide their inpatient services primarily at the hospital.

29 “(ii) SIGNIFICANT ADVERSE IMPACT IN ABSENCE OF
30 HOSPITAL.—If the hospital were to close—

31 “(I) there would be a significant amount of time
32 needed for residents to reach emergency treatment, re-
33 sulting in a potential significant harm to beneficiaries
34 with critical illnesses or injuries;

35 “(II) there would be an inability in the community
36 to stabilize emergency cases for transfers to another

1 acute care setting, resulting in a potential for signifi-
2 cant harm to medicare beneficiaries; and

3 “(III) any other nearby hospital lacks the physical
4 and clinical capacity to take over the hospital’s typical
5 admissions.

6 “(C) In making such determination, the Secretary may
7 also consider the following:

8 “(i) Free-standing ambulatory surgery centers, office-
9 based oncology care, and imaging center services are insuf-
10 ficient in the hospital’s area to handle the outpatient care
11 of the hospital.

12 “(ii) Beneficiaries in nearby areas would be adversely
13 affected if the hospital were to close as the hospital pro-
14 vides specialized knowledge and services to a network of
15 smaller hospitals and critical access hospitals.

16 “(iii) Medicare beneficiaries would have difficulty in
17 accessing care if the hospital were to close as the hospital
18 provides significant subsidies to support ambulatory care in
19 local clinics, including mental health clinics and to support
20 post acute care.

21 “(iv) The hospital has a committment to provide grad-
22 uate medical education in a rural area.

23 “(C) QUALITY CARE.—The hospital inpatient score for
24 quality of care is not less than the median hospital score
25 for qualify of care for hospitals in the State, as established
26 under standards of the utilization and quality control peer
27 review organization under part B of title XI or other qual-
28 ity standards recognized by the Secretary.

29 A hospital classified as an essential rural hospital may not
30 change such classification and a hospital so classified shall not
31 be treated as a sole community hospital, medicare dependent
32 hospital, or rural referral center for purposes of section 1886.”.

33 (b) PAYMENT BASED ON 102 PERCENT OF ALLOWED
34 COSTS.—

35 (1) INPATIENT HOSPITAL SERVICES.—Section 1886(d)
36 (42 U.S.C. 1395ww(d)) is amended by adding at the end
37 the following:

1 “(11) In the case of a hospital classified as an essential
2 rural hospital under section 1861(mm)(4) for a cost reporting
3 period, the payment under this subsection for inpatient hospital
4 services for discharges occurring during the period shall be
5 based on 102 percent of the reasonable costs for such services.
6 Nothing in this paragraph shall be construed as affecting the
7 application or amount of deductibles or copayments otherwise
8 applicable to such services under part A or as waiving any re-
9 quirement for billing for such services.”.

10 (2) HOSPITAL OUTPATIENT SERVICES.—Section
11 1833(t)(13) (42 U.S.C. 1395l(t)(13)) is amended by add-
12 ing at the end the following new subparagraph:

13 “(B) SPECIAL RULE FOR ESSENTIAL RURAL HOS-
14 PITALS.—In the case of a hospital classified as an es-
15 sential rural hospital under section 1861(mm)(4) for a
16 cost reporting period, the payment under this sub-
17 section for covered OPD services during the period
18 shall be based on 102 percent of the reasonable costs
19 for such services. Nothing in this subparagraph shall be
20 construed as affecting the application or amount of
21 deductibles or copayments otherwise applicable to such
22 services under this part or as waiving any requirement
23 for billing for such services.”.

24 (c) EFFECTIVE DATE.—The amendments made by this
25 section shall apply to cost reporting periods beginning on or
26 after October 1, 2004.

27 **SEC. 404. MORE FREQUENT UPDATE IN WEIGHTS USED**
28 **IN HOSPITAL MARKET BASKET.**

29 (a) MORE FREQUENT UPDATES IN WEIGHTS.—After re-
30 vising the weights used in the hospital market basket under
31 section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C.
32 1395ww(b)(3)(B)(iii)) to reflect the most current data avail-
33 able, the Secretary shall establish a frequency for revising such
34 weights, including the labor share, in such market basket to re-
35 flect the most current data available more frequently than once
36 every 5 years.

(b) REPORT.—Not later than October 1, 2004, the Secretary shall submit a report to Congress on the frequency established under subsection (a), including an explanation of the reasons for, and options considered, in determining such frequency.

SEC. 405. IMPROVEMENTS TO CRITICAL ACCESS HOSPITAL PROGRAM.

(a) INCREASE IN PAYMENT AMOUNTS.—

(1) IN GENERAL.—Sections 1814(l), 1834(g)(1), and 1883(a)(3) (42 U.S.C. 1395f(l); 1395m(g)(1); 42 U.S.C. 1395tt(a)(3)) are each amended by inserting “equal to 102 percent of” before “the reasonable costs”.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to payments for services furnished during cost reporting periods beginning on or after October 1, 2003.

(b) COVERAGE OF COSTS FOR CERTAIN EMERGENCY ROOM ON-CALL PROVIDERS.—

(1) IN GENERAL.—Section 1834(g)(5) (42 U.S.C. 1395m(g)(5)) is amended—

(A) in the heading—

(i) by inserting “CERTAIN” before “EMERGENCY”; and

(ii) by striking “PHYSICIANS” and inserting “PROVIDERS”;

(B) by striking “emergency room physicians who are on-call (as defined by the Secretary)” and inserting “physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services”; and

(C) by striking “physicians’ services” and inserting “services covered under this title”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to costs incurred for services provided on or after January 1, 2004.

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1 (c) MODIFICATION OF THE ISOLATION TEST FOR COST-
2 BASED CAH AMBULANCE SERVICES.—

3 (1) IN GENERAL.—Section 1834(l)(8) (42 U.S.C.
4 1395m(l)), as added by section 205(a) of BIPA (114 Stat.
5 2763A–482), is amended by adding at the end the fol-
6 lowing: “The limitation described in the matter following
7 subparagraph (B) in the previous sentence shall not apply
8 if the ambulance services are furnished by such a provider
9 or supplier of ambulance services who is a first responder
10 to emergencies (as determined by the Secretary).”.

11 (2) EFFECTIVE DATE.—The amendment made by
12 paragraph (1) shall apply to ambulances services furnished
13 on or after the first cost reporting period that begins after
14 the date of the enactment of this Act.

15 (d) REINSTATEMENT OF PERIODIC INTERIM PAYMENT
16 (PIP).—

17 (1) IN GENERAL.—Section 1815(e)(2) (42 U.S.C.
18 1395g(e)(2)) is amended—

19 (A) in the matter before subparagraph (A), by in-
20 serting “, in the cases described in subparagraphs (A)
21 through (D)” after “1986”; and

22 (B) by striking “and” at the end of subparagraph
23 (C);

24 (C) by adding “and” at the end of subparagraph
25 (D); and

26 (D) by inserting after subparagraph (D) the fol-
27 lowing new subparagraph:

28 “(E) inpatient critical access hospital services;”.

29 (2) DEVELOPMENT OF ALTERNATIVE METHODS OF
30 PERIODIC INTERIM PAYMENTS.—With respect to periodic
31 interim payments to critical access hospitals for inpatient
32 critical access hospital services under section 1815(e)(2)(E)
33 of the Social Security Act, as added by paragraph (1), the
34 Secretary shall develop alternative methods for such pay-
35 ments that are based on expenditures of the hospital.

1 (3) REINSTATEMENT OF PIP.—The amendments made
2 by paragraph (1) shall apply to payments made on or after
3 January 1, 2004.

4 (e) CONDITION FOR APPLICATION OF SPECIAL PHYSICIAN
5 PAYMENT ADJUSTMENT.—

6 (1) IN GENERAL.—Section 1834(g)(2) (42 U.S.C.
7 1395m(g)(2)) is amended by adding after and below sub-
8 paragraph (B) the following:

9 “The Secretary may not require, as a condition for apply-
10 ing subparagraph (B) with respect to a critical access hos-
11 pital, that each physician providing professional services in
12 the hospital must assign billing rights with respect to such
13 services, except that such subparagraph shall not apply to
14 those physicians who have not assigned such billing
15 rights.”.

16 (2) EFFECTIVE DATE.—The amendment made by
17 paragraph (1) shall be effective as if included in the enact-
18 ment of section 403(d) of the Medicare, Medicaid, and
19 SCHIP Balanced Budget Refinement Act of 1999 (113
20 Stat. 1501A–371).

21 (f) FLEXIBILITY IN BED LIMITATION FOR HOSPITALS.—
22 Section 1820 (42 U.S.C. 1395i–4) is amended—

23 (1) in subsection (c)(2)(B)(iii), by inserting “subject
24 to paragraph (3)” after “(iii) provides”;

25 (2) by adding at the end of subsection (c) the fol-
26 lowing new paragraph:

27 “(3) INCREASE IN MAXIMUM NUMBER OF BEDS FOR
28 HOSPITALS WITH STRONG SEASONAL CENSUS FLUCTUA-
29 TIONS.—

30 “(A) IN GENERAL.—Subject to subparagraph (C),
31 in the case of a hospital that demonstrates that it
32 meets the standards established under subparagraph
33 (B) and has not made the election described in sub-
34 section (f)(2)(A), the bed limitations otherwise applica-
35 ble under paragraph (2)(B)(iii) and subsection (f) shall
36 be increased by 5 beds.

1 “(B) STANDARDS.—The Secretary shall specify
2 standards for determining whether a critical access hos-
3 pital has sufficiently strong seasonal variations in pa-
4 tient admissions to justify the increase in bed limitation
5 provided under subparagraph (A).”; and

6 (3) in subsection (f)—

7 (A) by inserting “(1)” after “(f)”; and

8 (B) by adding at the end the following new para-
9 graph:

10 “(2)(A) A hospital may elect to treat the reference in
11 paragraph (1) to ‘15 beds’ as a reference to ‘25 beds’, but only
12 if no more than 10 beds in the hospital are at any time used
13 for non-acute care services. A hospital that makes such an elec-
14 tion is not eligible for the increase provided under subsection
15 (c)(3)(A).

16 “(B) The limitations in numbers of beds under the first
17 sentence of paragraph (1) are subject to adjustment under sub-
18 section (c)(3).”.

19 (4) EFFECTIVE DATE.—The amendments made by
20 this subsection shall apply to designations made before, on,
21 or after January 1, 2004.

22 (g) ADDITIONAL 5-YEAR PERIOD OF FUNDING FOR
23 GRANT PROGRAM.—

24 (1) IN GENERAL.—Section 1820(g) (42 U.S.C. 1395i-
25 4(g)) is amended by adding at the end the following new
26 paragraph:

27 “(4) FUNDING.—

28 “(A) IN GENERAL.—Subject to subparagraph (B),
29 payment for grants made under this subsection during
30 fiscal years 2004 through 2008 shall be made from the
31 Federal Hospital Insurance Trust Fund.

32 “(B) ANNUAL AGGREGATE LIMITATION.—In no
33 case may the amount of payment provided for under
34 subparagraph (A) for a fiscal year exceed
35 \$25,000,000.”.

36 (2) CONFORMING AMENDMENT.—Section 1820 (42
37 U.S.C. 1395i-4) is amended by striking subsection (j).

1 **SEC. 406. REDISTRIBUTION OF UNUSED RESIDENT POSI-**
2 **TIONS.**

3 (a) IN GENERAL.—Section 1886(h)(4) (42 U.S.C.
4 1395ww(h)(4)) is amended—

5 (1) in subparagraph (F)(i), by inserting “subject to
6 subparagraph (I),” after “October 1, 1997,”;

7 (2) in subparagraph (H)(i), by inserting “subject to
8 subparagraph (I),” after “subparagraphs (F) and (G),”;
9 and

10 (3) by adding at the end the following new subpara-
11 graph:

12 “(I) REDISTRIBUTION OF UNUSED RESIDENT PO-
13 SITIONS.—

14 “(i) REDUCTION IN LIMIT BASED ON UNUSED
15 POSITIONS.—

16 “(I) IN GENERAL.—If a hospital’s resident
17 level (as defined in clause (iii)(I)) is less than
18 the otherwise applicable resident limit (as de-
19 fined in clause (iii)(II)) for each of the ref-
20 erence periods (as defined in subclause (II)),
21 effective for cost reporting periods beginning on
22 or after January 1, 2004, the otherwise appli-
23 cable resident limit shall be reduced by 75 per-
24 cent of the difference between such limit and
25 the reference resident level specified in sub-
26 clause (III) (or subclause (IV) if applicable).

27 “(II) REFERENCE PERIODS DEFINED.—In
28 this clause, the term ‘reference periods’ means,
29 for a hospital, the 3 most recent consecutive
30 cost reporting periods of the hospital for which
31 cost reports have been settled (or, if not, sub-
32 mitted) on or before September 30, 2002.

33 “(III) REFERENCE RESIDENT LEVEL.—
34 Subject to subclause (IV), the reference resi-
35 dent level specified in this subclause for a hos-
36 pital is the highest resident level for the hos-
37 pital during any of the reference periods.

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1 “(IV) ADJUSTMENT PROCESS.—Upon the
2 timely request of a hospital, the Secretary may
3 adjust the reference resident level for a hospital
4 to be the resident level for the hospital for the
5 cost reporting period that includes July 1,
6 2003.

7 “(V) AFFILIATION.—With respect to hos-
8 pitals which are members of the same affiliated
9 group (as defined by the Secretary under sub-
10 paragraph (H)(ii)), the provisions of this sec-
11 tion shall be applied with respect to such an af-
12 filiated group by deeming the affiliated group
13 to be a single hospital.

14 “(ii) REDISTRIBUTION.—

15 “(I) IN GENERAL.—The Secretary is au-
16 thorized to increase the otherwise applicable
17 resident limits for hospitals by an aggregate
18 number estimated by the Secretary that does
19 not exceed the aggregate reduction in such lim-
20 its attributable to clause (i) (without taking
21 into account any adjustment under subclause
22 (IV) of such clause).

23 “(II) EFFECTIVE DATE.—No increase
24 under subclause (I) shall be permitted or taken
25 into account for a hospital for any portion of
26 a cost reporting period that occurs before July
27 1, 2004, or before the date of the hospital’s ap-
28 plication for an increase under this clause. No
29 such increase shall be permitted for a hospital
30 unless the hospital has applied to the Secretary
31 for such increase by December 31, 2005.

32 “(III) CONSIDERATIONS IN REDISTRIBU-
33 TION.—In determining for which hospitals the
34 increase in the otherwise applicable resident
35 limit is provided under subclause (I), the Sec-
36 retary shall take into account the need for such

1 an increase by specialty and location involved,
2 consistent with subclause (IV).

3 “(IV) PRIORITY FOR RURAL AND SMALL
4 URBAN AREAS.—In determining for which hos-
5 pitals and residency training programs an in-
6 crease in the otherwise applicable resident limit
7 is provided under subclause (I), the Secretary
8 shall first distribute the increase to programs
9 of hospitals located in rural areas or in urban
10 areas that are not large urban areas (as de-
11 fined for purposes of subsection (d)) and to
12 programs that have no other program of the
13 same specialty in the same state, on a first-
14 come-first-served basis (as determined by the
15 Secretary) based on a demonstration that the
16 hospital will fill the positions made available
17 under this clause and not to exceed an increase
18 of 25 full-time equivalent positions with respect
19 to any hospital.

20 “(V) APPLICATION OF LOCALITY AD-
21 JUSTED NATIONAL AVERAGE PER RESIDENT
22 AMOUNT.—With respect to additional residency
23 positions in a hospital attributable to the in-
24 crease provided under this clause, notwith-
25 standing any other provision of this subsection,
26 the approved FTE resident amount is deemed
27 to be equal to the locality adjusted national av-
28 erage per resident amount computed under
29 subparagraph (E) for that hospital.

30 “(VI) CONSTRUCTION.—Nothing in this
31 clause shall be construed as permitting the re-
32 distribution of reductions in residency positions
33 attributable to voluntary reduction programs
34 under paragraph (6) or as affecting the ability
35 of a hospital to establish new medical residency
36 training programs under subparagraph (H).

1 “(iii) RESIDENT LEVEL AND LIMIT DE-
2 FINED.—In this subparagraph:

3 “(I) RESIDENT LEVEL.—The term ‘resi-
4 dent level’ means, with respect to a hospital,
5 the total number of full-time equivalent resi-
6 dents, before the application of weighting fac-
7 tors (as determined under this paragraph), in
8 the fields of allopathic and osteopathic medi-
9 cine for the hospital.

10 “(II) OTHERWISE APPLICABLE RESIDENT
11 LIMIT.—The term ‘otherwise applicable resi-
12 dent limit’ means, with respect to a hospital,
13 the limit otherwise applicable under subpara-
14 graphs (F)(i) and (H) on the resident level for
15 the hospital determined without regard to this
16 subparagraph.”.

17 (b) CONFORMING AMENDMENT TO IME.—Section
18 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is amended
19 by adding at the end the following: “The provisions of subpara-
20 graph (I) of subsection (h)(4) shall apply with respect to the
21 first sentence of this clause in the same manner as it applies
22 with respect to subparagraph (F) of such subsection.”.

23 (c) REPORT ON EXTENSION OF APPLICATIONS UNDER
24 REDISTRIBUTION PROGRAM.—Not later than July 1, 2005, the
25 Secretary shall submit to Congress a report containing rec-
26 ommendations regarding whether to extend the deadline for ap-
27 plications for an increase in resident limits under section
28 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by
29 subsection (a)).

30 **SEC. 407. TWO-YEAR EXTENSION OF HOLD HARMLESS**
31 **PROVISIONS FOR SMALL RURAL HOSPITALS**
32 **AND SOLE COMMUNITY HOSPITALS UNDER**
33 **PROSPECTIVE PAYMENT SYSTEM FOR HOS-**
34 **PITAL OUTPATIENT DEPARTMENT SERV-**
35 **ICES.**

36 (a) HOLD HARMLESS PROVISIONS.—

37 (1) IN GENERAL.—Section 1833(t)(7)(D)(i) (42
38 U.S.C. 1395l(t)(7)(D)(i)) is amended—

1 (A) in the heading, by striking “SMALL” and in-
2 serting “CERTAIN”;

3 (B) by inserting “or a sole community hospital (as
4 defined in section 1886(d)(5)(D)(iii)) located in a rural
5 area” after “100 beds”; and

6 (C) by striking “2004” and inserting “2006”.

7 (2) EFFECTIVE DATE.—The amendment made by sub-
8 section (a)(2) shall apply with respect to payment for OPD
9 services furnished on and after January 1, 2004.

10 (b) STUDY; ADJUSTMENT.—

11 (1) STUDY.—The Secretary shall conduct a study to
12 determine if, under the prospective payment system for
13 hospital outpatient department services under section
14 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)),
15 costs incurred by rural providers of services by ambulatory
16 payment classification groups (APCs) exceed those costs in-
17 curred by urban providers of services.

18 (2) ADJUSTMENT.—Insofar as the Secretary deter-
19 mines under paragraph (1) that costs incurred by rural
20 providers exceed those costs incurred by urban providers of
21 services, the Secretary shall provide for an appropriate ad-
22 justment under such section 1833(t) to reflect those higher
23 costs by January 1, 2005.

24 **SEC. 408. EXCLUSION OF CERTAIN RURAL HEALTH CLIN-**
25 **IC AND FEDERALLY QUALIFIED HEALTH**
26 **CENTER SERVICES FROM THE PROSPECTIVE**
27 **PAYMENT SYSTEM FOR SKILLED NURSING**
28 **FACILITIES.**

29 (a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C.
30 1395yy(e)(2)(A)) is amended—

31 (1) in clause (i)(II), by striking “clauses (ii) and (iii)”
32 and inserting “clauses (ii), (iii), and (iv)”; and

33 (2) by adding at the end the following new clause:

34 “(iv) EXCLUSION OF CERTAIN RURAL HEALTH
35 CLINIC AND FEDERALLY QUALIFIED HEALTH CEN-
36 TER SERVICES.—Services described in this clause
37 are—

1 “(I) rural health clinic services (as defined
2 in paragraph (1) of section 1861(aa)); and

3 “(II) Federally qualified health center
4 services (as defined in paragraph (3) of such
5 section);

6 that would be described in clause (ii) if such serv-
7 ices were not furnished by an individual affiliated
8 with a rural health clinic or a Federally qualified
9 health center.”.

10 (b) EFFECTIVE DATE.—The amendments made by sub-
11 section (a) shall apply to services furnished on or after January
12 1, 2004.

13 **SEC. 409. RECOGNITION OF ATTENDING NURSE PRACTI-**
14 **TIONERS AS ATTENDING PHYSICIANS TO**
15 **SERVE HOSPICE PATIENTS.**

16 (a) IN GENERAL.—Section 1861(dd)(3)(B) (42 U.S.C.
17 1395x(dd)(3)(B)) is amended by inserting “or nurse practi-
18 tioner (as defined in subsection (aa)(5))” after “the physician
19 (as defined in subsection (r)(1))”.

20 (b) PROHIBITION ON NURSE PRACTITIONER CERTIFYING
21 NEED FOR HOSPICE.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C.
22 1395f(a)(7)(A)(i)(I)) is amended by inserting “(which for pur-
23 poses of this subparagraph does not include a nurse practi-
24 tioner)” after “attending physician (as defined in section
25 1861(dd)(3)(B))”.

26 **SEC. 410. IMPROVEMENT IN PAYMENTS TO RETAIN**
27 **EMERGENCY CAPACITY FOR AMBULANCE**
28 **SERVICES IN RURAL AREAS.**

29 Section 1834(l) (42 U.S.C. 1395m(l)) is amended—

30 (1) by redesignating paragraph (8), as added by sec-
31 tion 221(a) of BIPA (114 Stat. 2763A–486), as paragraph
32 (9); and

33 (2) by adding at the end the following new paragraph:

34 “(10) ASSISTANCE FOR RURAL PROVIDERS FUR-
35 NISHING SERVICES IN LOW MEDICARE POPULATION DEN-
36 SITY AREAS.—

37 “(A) IN GENERAL.—In the case of ground ambu-
38 lance services furnished on or after January 1, 2004,

1 for which the transportation originates in a qualified
2 rural area (as defined in subparagraph (B)), the Sec-
3 retary shall provide for an increase in the base rate of
4 the fee schedule for mileage for a trip established under
5 this subsection. In establishing such increase, the Sec-
6 retary shall, based on the relationship of cost and vol-
7 ume, estimate the average increase in cost per trip for
8 such services as compared with the cost per trip for the
9 average ambulance service.

10 “(B) QUALIFIED RURAL AREA DEFINED.—For
11 purposes of subparagraph (A), the term ‘qualified rural
12 area’ is a rural area (as defined in section
13 1886(d)(2)(D)) with a population density of medicare
14 beneficiaries residing in the area that is in the lowest
15 three quartiles of all rural county populations.”.

16 **SEC. 411. PROVIDING SAFE HARBOR FOR CERTAIN COL-**
17 **LABORATIVE EFFORTS THAT BENEFIT MEDI-**
18 **CALLY UNDERSERVED POPULATIONS.**

19 (a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C.
20 1320a-7(b)(3)), as amended by section 101(b)(2), is
21 amended—

22 (1) in subparagraph (F), by striking “and” after the
23 semicolon at the end;

24 (2) in subparagraph (G), by striking the period at the
25 end and inserting “; and”; and

26 (3) by adding at the end the following new subpara-
27 graph:

28 “(H) any remuneration between a public or non-
29 profit private health center entity described under
30 clause (i) or (ii) of section 1905(l)(2)(B) and any indi-
31 vidual or entity providing goods, items, services, dona-
32 tions or loans, or a combination thereof, to such health
33 center entity pursuant to a contract, lease, grant, loan,
34 or other agreement, if such agreement contributes to
35 the ability of the health center entity to maintain or in-
36 crease the availability, or enhance the quality, of serv-

1 ices provided to a medically underserved population
2 served by the health center entity.”.

3 (b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER
4 ENTITY ARRANGEMENTS.—

5 (1) ESTABLISHMENT.—

6 (A) IN GENERAL.—The Secretary of Health and
7 Human Services (in this subsection referred to as the
8 “Secretary”) shall establish, on an expedited basis,
9 standards relating to the exception described in section
10 1128B(b)(3)(H) of the Social Security Act, as added
11 by subsection (a), for health center entity arrangements
12 to the antikickback penalties.

13 (B) FACTORS TO CONSIDER.—The Secretary shall
14 consider the following factors, among others, in estab-
15 lishing standards relating to the exception for health
16 center entity arrangements under subparagraph (A):

17 (i) Whether the arrangement between the
18 health center entity and the other party results in
19 savings of Federal grant funds or increased reve-
20 nues to the health center entity.

21 (ii) Whether the arrangement between the
22 health center entity and the other party restricts or
23 limits a patient’s freedom of choice.

24 (iii) Whether the arrangement between the
25 health center entity and the other party protects a
26 health care professional’s independent medical
27 judgment regarding medically appropriate treat-
28 ment.

29 The Secretary may also include other standards and
30 criteria that are consistent with the intent of Congress
31 in enacting the exception established under this section.

32 (2) INTERIM FINAL EFFECT.—No later than 180 days
33 after the date of enactment of this Act, the Secretary shall
34 publish a rule in the Federal Register consistent with the
35 factors under paragraph (1)(B). Such rule shall be effective
36 and final immediately on an interim basis, subject to such
37 change and revision, after public notice and opportunity

1 (for a period of not more than 60 days) for public com-
2 ment, as is consistent with this subsection.

3 **SEC. 412. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN**
4 **PAYMENTS FOR PHYSICIANS' SERVICES.**

5 (a) STUDY.—The Comptroller General of the United
6 States shall conduct a study of differences in payment amounts
7 under the physician fee schedule under section 1848 of the So-
8 cial Security Act (42 U.S.C. 1395w-4) for physicians' services
9 in different geographic areas. Such study shall include—

10 (1) an assessment of the validity of the geographic ad-
11 justment factors used for each component of the fee sched-
12 ule;

13 (2) an evaluation of the measures used for such ad-
14 justment, including the frequency of revisions; and

15 (3) an evaluation of the methods used to determine
16 professional liability insurance costs used in computing the
17 malpractice component, including a review of increases in
18 professional liability insurance premiums and variation in
19 such increases by State and physician specialty and meth-
20 ods used to update the geographic cost of practice index
21 and relative weights for the malpractice component.

22 (b) REPORT.—Not later than 1 year after the date of the
23 enactment of this Act, the Comptroller General shall submit to
24 Congress a report on the study conducted under subsection (a).
25 The report shall include recommendations regarding the use of
26 more current data in computing geographic cost of practice in-
27 dices as well as the use of data directly representative of physi-
28 cians' costs (rather than proxy measures of such costs).

29 **SEC. 413. TREATMENT OF MISSING COST REPORTING**
30 **PERIODS FOR SOLE COMMUNITY HOS-**
31 **PITALS.**

32 (a) IN GENERAL.—Section 1886(b)(3)(I) (42 U.S.C.
33 1395ww(b)(3)(I)) is amended by adding at the end the fol-
34 lowing new clause:

35 “(iii) In no case shall a hospital be denied treatment as
36 a sole community hospital or payment (on the basis of a target
37 rate as such as a hospital) because data are unavailable for any

1 cost reporting period due to changes in ownership, changes in
2 fiscal intermediaries, or other extraordinary circumstances, so
3 long as data for at least one applicable base cost reporting pe-
4 riod is available.”.

5 (b) EFFECTIVE DATE.—The amendment made by sub-
6 section (a) shall apply to cost reporting periods beginning on
7 or after January 1, 2004.

8 **SEC. 414. EXTENSION OF TELEMEDICINE DEMONSTRA-**
9 **TION PROJECT.**

10 Section 4207 of Balanced Budget Act of 1997 (Public
11 Law 105–33) is amended—

12 (1) in subsection (a)(4), by striking “4-year” and in-
13 serting “8-year”; and

14 (2) in subsection (d)(3), by striking “\$30,000,000”
15 and inserting “\$60,000,000”.

16 **TITLE V—PROVISIONS RELATING**
17 **TO PART A**
18 **Subtitle A—Inpatient Hospital**
19 **Services**

20 **SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAY-**
21 **MENT UPDATES.**

22 Section 1886(b)(3)(B)(i) (42 U.S.C. 1395ww(b)(3)(B)(i))
23 is amended—

24 (1) by striking “and” at the end of subclause (XVIII);

25 (2) by striking subclause (XIX); and

26 (3) by inserting after subclause (XVIII) the following
27 new subclauses:

28 “(XIX) for each of fiscal years 2004 through 2006,
29 the market basket percentage increase minus 0.4 percent-
30 age points for hospitals in all areas; and

31 “(XX) for fiscal year 2007 and each subsequent fiscal
32 year, the market basket percentage increase for hospitals in
33 all areas.”.

1 **SEC. 502. RECOGNITION OF NEW MEDICAL TECH-**
2 **NOLOGIES UNDER INPATIENT HOSPITAL**
3 **PPS.**

4 (a) IMPROVING TIMELINESS OF DATA COLLECTION.—Sec-
5 tion 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended
6 by adding at the end the following new clause:

7 “(vii) Under the mechanism under this subparagraph, the
8 Secretary shall provide for the addition of new diagnosis and
9 procedure codes in April 1 of each year, but the addition of
10 such codes shall not require the Secretary to adjust the pay-
11 ment (or diagnosis-related group classification) under this sub-
12 section until the fiscal year that begins after such date.”.

13 (b) ELIGIBILITY STANDARD FOR TECHNOLOGY
14 OUTLIERS.—

15 (1) MINIMUM PERIOD FOR RECOGNITION OF NEW
16 TECHNOLOGIES.—Section 1886(d)(5)(K)(vi) (42 U.S.C.
17 1395ww(d)(5)(K)(vi)) is amended—

18 (A) by inserting “(I)” after “(vi)”; and

19 (B) by adding at the end the following new sub-
20 clause:

21 “(II) Under such criteria, a service or technology shall not
22 be denied treatment as a new service or technology on the basis
23 of the period of time in which the service or technology has
24 been in use if such period ends before the end of the 2-to-3-
25 year period that begins on the effective date of implementation
26 of a code under ICD–9–CM (or a successor coding method-
27 ology) that enables the identification of specific discharges in
28 which the service or technology has been used.”.

29 (2) ADJUSTMENT OF THRESHOLD.—Section
30 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is
31 amended by inserting “(applying a threshold specified by
32 the Secretary that is 75 percent of one standard deviation
33 for the diagnosis-related group involved)” after “is inad-
34 equate”.

35 (3) CRITERION FOR SUBSTANTIAL IMPROVEMENT.—
36 Section 1886(d)(5)(K)(vi) (42 U.S.C.
37 1395ww(d)(5)(K)(vi)), as amended by paragraph (1), is

1 further amended by adding at the end the following sub-
2 clause:

3 “(III) The Secretary shall by regulation provide for fur-
4 ther clarification of the criteria applied to determine whether
5 a new service or technology represents an advance in medical
6 technology that substantially improves the diagnosis or treat-
7 ment of beneficiaries. Under such criteria, in determining
8 whether a new service or technology represents an advance in
9 medical technology that substantially improves the diagnosis or
10 treatment of beneficiaries, the Secretary shall deem a service
11 or technology as meeting such requirement if the service or
12 technology is a drug or biological that is designated under sec-
13 tion 506 of the Federal Food, Drug, and Cosmetic Act, ap-
14 proved under section 314.510 or 601.41 of title 21, Code of
15 Federal Regulations, or designated for priority review when the
16 marketing application for such drug or biological was filed or
17 is a medical device for which an exemption has been granted
18 under section 520(m) of such Act, or for which priority review
19 has been provided under section 515(d)(5) of such Act. Noth-
20 ing in this subclause shall be construed as effecting the author-
21 ity of the Secretary to determine whether items and services
22 are medically necessary and appropriate under section
23 1862(a)(1).”.

24 (4) PROCESS FOR PUBLIC INPUT.—Section
25 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended
26 by paragraph (1), is amended—

27 (A) in clause (i), by adding at the end the fol-
28 lowing: “Such mechanism shall be modified to meet the
29 requirements of clause (viii).”; and

30 (B) by adding at the end the following new clause:

31 “(viii) The mechanism established pursuant to clause (i)
32 shall be adjusted to provide, before publication of a proposed
33 rule, for public input regarding whether a new service or tech-
34 nology not described in the second sentence of clause (vi)(III)
35 represents an advance in medical technology that substantially
36 improves the diagnosis or treatment of beneficiaries as follows:

1 “(I) The Secretary shall make public and periodically
2 update a list of all the services and technologies for which
3 an application for additional payment under this subpara-
4 graph is pending.

5 “(II) The Secretary shall accept comments, rec-
6 ommendations, and data from the public regarding whether
7 the service or technology represents a substantial improve-
8 ment.

9 “(III) The Secretary shall provide for a meeting at
10 which organizations representing hospitals, physicians,
11 medicare beneficiaries, manufacturers, and any other inter-
12 ested party may present comments, recommendations, and
13 data to the clinical staff of the Centers for Medicare &
14 Medicaid Services before publication of a notice of proposed
15 rulemaking regarding whether service or technology rep-
16 resents a substantial improvement.”.

17 (c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—Sec-
18 tion 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is further
19 amended by adding at the end the following new clause:

20 “(ix) Before establishing any add-on payment under this
21 subparagraph with respect to a new technology, the Secretary
22 shall seek to identify one or more diagnosis-related groups as-
23 sociated with such technology, based on similar clinical or ana-
24 tomical characteristics and the cost of the technology. Within
25 such groups the Secretary shall assign an eligible new tech-
26 nology into a diagnosis-related group where the average costs
27 of care most closely approximate the costs of care of using the
28 new technology. In such case, the new technology would no
29 longer meet the threshold of exceeding 75 percent of the stand-
30 ard deviation for the diagnosis-related group involved under
31 clause (ii)(I). No add-on payment under this subparagraph
32 shall be made with respect to such new technology and this
33 clause shall not affect the application of paragraph
34 (4)(C)(iii).”.

35 (d) IMPROVEMENT IN PAYMENT FOR NEW TECH-
36 NOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C.
37 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after “the

1 estimated average cost of such service or technology” the fol-
2 lowing: “(based on the marginal rate applied to costs under
3 subparagraph (A))”.

4 (e) ESTABLISHMENT OF NEW FUNDING FOR HOSPITAL
5 INPATIENT TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42
6 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking “sub-
7 ject to paragraph (4)(C)(iii),”.

8 (f) EFFECTIVE DATE.—

9 (1) IN GENERAL.—The Secretary shall implement the
10 amendments made by this section so that they apply to
11 classification for fiscal years beginning with fiscal year
12 2005.

13 (2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL
14 YEAR 2003 THAT ARE DENIED.—In the case of an applica-
15 tion for a classification of a medical service or technology
16 as a new medical service or technology under section
17 1886(d)(5)(K) of the Social Security Act (42 U.S.C.
18 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and
19 that is denied—

20 (A) the Secretary shall automatically reconsider
21 the application as an application for fiscal year 2005
22 under the amendments made by this section; and

23 (B) the maximum time period otherwise permitted
24 for such classification of the service or technology shall
25 be extended by 12 months.

26 **SEC. 503. INCREASE IN FEDERAL RATE FOR HOSPITALS**
27 **IN PUERTO RICO.**

28 Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is
29 amended—

30 (1) in subparagraph (A)—

31 (A) in clause (i), by striking “for discharges begin-
32 ning on or after October 1, 1997, 50 percent (and for
33 discharges between October 1, 1987, and September
34 30, 1997, 75 percent)” and inserting “the applicable
35 Puerto Rico percentage (specified in subparagraph
36 (E))”; and

1 (B) in clause (ii), by striking “for discharges be-
2 ginning in a fiscal year beginning on or after October
3 1, 1997, 50 percent (and for discharges between Octo-
4 ber 1, 1987, and September 30, 1997, 25 percent)”
5 and inserting “the applicable Federal percentage (spec-
6 ified in subparagraph (E))”; and

7 (2) by adding at the end the following new subpara-
8 graph:

9 “(E) For purposes of subparagraph (A), for discharges
10 occurring—

11 “(i) on or after October 1, 1987, and before October
12 1, 1997, the applicable Puerto Rico percentage is 75 per-
13 cent and the applicable Federal percentage is 25 percent;

14 “(ii) on or after October 1, 1997, and before October
15 1, 2003, the applicable Puerto Rico percentage is 50 per-
16 cent and the applicable Federal percentage is 50 percent;

17 “(iii) during fiscal year 2004, the applicable Puerto
18 Rico percentage is 41 percent and the applicable Federal
19 percentage is 59 percent;

20 “(iv) during fiscal year 2005, the applicable Puerto
21 Rico percentage is 33 percent and the applicable Federal
22 percentage is 67 percent; and

23 “(v) on or after October 1, 2005, the applicable Puer-
24 to Rico percentage is 25 percent and the applicable Federal
25 percentage is 75 percent.”.

26 **SEC. 504. WAGE INDEX ADJUSTMENT RECLASSIFICA-**
27 **TION REFORM .**

28 (a) IN GENERAL.—Section 1886(d) (42 U.S.C.
29 1395ww(d)) is amended by adding at the end the following:

30 “(11)(A) In order to recognize commuting patterns among
31 Metropolitan Statistical Areas and between such Areas and
32 rural areas, the Secretary shall establish a process, upon appli-
33 cation of a subsection (d) hospital that establishes that it is a
34 qualifying hospital described in subparagraph (B), for an in-
35 crease of the wage index applied under paragraph (3)(E) for
36 the hospital in the amount computed under subparagraph (D).

1 “(B) A qualifying hospital described in this subparagraph
2 is a subsection (d) hospital—

3 “(i) the average wages of which exceed the average
4 wages for the area in which the hospital is located; and

5 “(ii) which has at least 10 percent of its employees
6 who reside in one or more higher wage index areas.

7 “(C) For purposes of this paragraph, the term ‘higher
8 wage index area’ means, with respect to a hospital, an area
9 with a wage index that exceeds that of the area in which the
10 hospital is located.

11 “(D) The increase in the wage index under subparagraph
12 (A) for a hospital shall be equal to the percentage of the em-
13 ployees of the hospital that resides in any higher wage index
14 area multiplied by the sum of the products, for each higher
15 wage index area of—

16 “(i) the difference between (I) the wage index for such
17 area, and (II) the wage index of the area in which the hos-
18 pital is located (before the application of this paragraph);
19 and

20 “(ii) the number of employees of the hospital that re-
21 side in such higher wage index area divided by the total
22 number of such employees that reside in all high wage
23 index areas.

24 “(E) The process under this paragraph shall be based
25 upon the process used by the Medicare Geographic Classifica-
26 tion Review Board under paragraph (10) with respect to data
27 submitted by hospitals to the Board on the location of resi-
28 dence of hospital employees and wages under the applicable
29 schedule established for geographic reclassification.

30 “(F) A reclassification under this paragraph shall be effec-
31 tive for a period of 3 fiscal years, except that the Secretary
32 shall establish procedures under which a subsection (d) hospital
33 may elect to terminate such reclassification before the end of
34 such period.

35 “(G) A hospital that is reclassified under this paragraph
36 for a period is not eligible for reclassification under paragraphs
37 (8) or (10) during that period.

1 “(H) Any increase in a wage index under this paragraph
2 for a hospital shall not be taken into account for purposes of—

3 “(i) computing the wage index for the area in which
4 the hospital is located or any other area; or

5 “(ii) applying any budget neutrality adjustment with
6 respect to such index under paragraph (8)(D).”.

7 (b) EFFECTIVE DATE.—The amendment made by sub-
8 section (a) shall first apply to the wage index for cost reporting
9 period beginning on or after October 1, 2004.

10 **SEC. 505. MEDPAC REPORT ON SPECIALTY HOSPITALS.**

11 (a) MEDPAC STUDY.—The Medicare Payment Advisory
12 Commission shall conduct a study of specialty hospitals com-
13 pared with other similar general acute care hospitals under the
14 medicare program. Such study shall examine—

15 (1) whether there are excessive self-referrals;

16 (2) quality of care furnished;

17 (3) the impact of specialty hospitals on such general
18 acute care hospitals; and

19 (4) differences in the scope of services, medicaid utili-
20 zation, and uncompensated care furnished.

21 (b) REPORT.—Not later than 1 year after the date of the
22 enactment of this Act, the Secretary shall submit to Congress
23 a report on the study conducted under subsection (a), and shall
24 include any recommendations for legislation or administrative
25 change as the Secretary determines appropriate.

26 **Subtitle B—Other Provisions**

27 **SEC. 511. PAYMENT FOR COVERED SKILLED NURSING**
28 **FACILITY SERVICES.**

29 (a) ADJUSTMENT TO RUGs FOR AIDS RESIDENTS.—
30 Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is
31 amended to read as follows:

32 “(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

33 “(A) IN GENERAL.—Subject to subparagraph (B),
34 in the case of a resident of a skilled nursing facility
35 who is afflicted with acquired immune deficiency syn-
36 drome (AIDS), the per diem amount of payment other-

1 wise applicable shall be increased by 128 percent to re-
2 flect increased costs associated with such residents.

3 “(B) SUNSET.—Subparagraph (A) shall not apply
4 on and after such date as the Secretary certifies that
5 there is an appropriate adjustment in the case mix
6 under paragraph (4)(G)(i) to compensate for the in-
7 creased costs associated with residents described in
8 such subparagraph.”.

9 (b) EFFECTIVE DATE.—The amendment made by para-
10 graph (1) shall apply to services furnished on or after October
11 1, 2003.

12 **SEC. 512. COVERAGE OF HOSPICE CONSULTATION SERV-**
13 **ICES.**

14 (a) COVERAGE OF HOSPICE CONSULTATION SERVICES.—
15 Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

16 (1) by striking “and” at the end of paragraph (3);

17 (2) by striking the period at the end of paragraph (4)
18 and inserting “; and”; and

19 (3) by inserting after paragraph (4) the following new
20 paragraph:

21 “(5) for individuals who are terminally ill, have not
22 made an election under subsection (d)(1), and have not
23 previously received services under this paragraph, services
24 that are furnished by a physician who is either the medical
25 director or an employee of a hospice program and that con-
26 sist of—

27 “(A) an evaluation of the individual’s need for
28 pain and symptom management;

29 “(B) counseling the individual with respect to end-
30 of-life issues and care options; and

31 “(C) advising the individual regarding advanced
32 care planning.”.

33 (b) PAYMENT.—Section 1814(i) (42 U.S.C. 1395f(i)) is
34 amended by adding at the end the following new paragraph:

35 “(4) The amount paid to a hospice program with respect
36 to the services under section 1812(a)(5) for which payment
37 may be made under this part shall be equal to an amount

1 equivalent to the amount established for an office or other out-
2 patient visit for evaluation and management associated with
3 presenting problems of moderate severity under the fee sched-
4 ule established under section 1848(b), other than the portion
5 of such amount attributable to the practice expense compo-
6 nent.”.

7 (c) CONFORMING AMENDMENT.—Section
8 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended
9 by inserting before the comma at the end the following: “and
10 services described in section 1812(a)(5)”.

11 (d) EFFECTIVE DATE.—The amendments made by this
12 section shall apply to services provided by a hospice program
13 on or after January 1, 2004.

14 **TITLE VI—PROVISIONS RELATING**
15 **TO PART B**
16 **Subtitle A—Physicians’ Services**

17 **SEC. 601. REVISION OF UPDATES FOR PHYSICIANS’**
18 **SERVICES.**

19 (a) UPDATE FOR 2004 AND 2005.—

20 (1) IN GENERAL.—Section 1848(d) (42 U.S.C.
21 1395w-4(d)) is amended by adding at the end the following
22 new paragraph:

23 “(5) UPDATE FOR 2004 AND 2005.—The update to the
24 single conversion factor established in paragraph (1)(C) for
25 each of 2004 and 2005 shall be not less than 1.5 percent.”.

26 (2) CONFORMING AMENDMENT.—Paragraph (4)(B) of
27 such section is amended, in the matter before clause (i), by
28 inserting “and paragraph (5)” after “subparagraph (D)”.

29 (3) NOT TREATED AS CHANGE IN LAW AND REGULA-
30 TION IN SUSTAINABLE GROWTH RATE DETERMINATION.—
31 The amendments made by this subsection shall not be
32 treated as a change in law for purposes of applying section
33 1848(f)(2)(D) of the Social Security Act (42 U.S.C.
34 1395w-4(f)(2)(D)).

35 (b) USE OF 10-YEAR ROLLING AVERAGE IN COMPUTING
36 GROSS DOMESTIC PRODUCT.—

203

1 (1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C.
2 1395w-4(f)(2)(C)) is amended—

3 (A) by striking “projected” and inserting “annual
4 average”; and

5 (B) by striking “from the previous applicable pe-
6 riod to the applicable period involved” and inserting
7 “during the 10-year period ending with the applicable
8 period involved”.

9 (2) EFFECTIVE DATE.—The amendment made by
10 paragraph (1) shall apply to computations of the sustain-
11 able growth rate for years beginning with 2003.

12 **SEC. 602. STUDIES ON ACCESS TO PHYSICIANS’ SERV-**
13 **ICES.**

14 (a) GAO STUDY ON BENEFICIARY ACCESS TO PHYSI-
15 CIANS’ SERVICES.—

16 (1) STUDY.—The Comptroller General of the United
17 States shall conduct a study on access of medicare bene-
18 ficiaries to physicians’ services under the medicare pro-
19 gram. The study shall include—

20 (A) an assessment of the use by beneficiaries of
21 such services through an analysis of claims submitted
22 by physicians for such services under part B of the
23 medicare program;

24 (B) an examination of changes in the use by bene-
25 ficiaries of physicians’ services over time;

26 (C) an examination of the extent to which physi-
27 cians are not accepting new medicare beneficiaries as
28 patients.

29 (2) REPORT.—Not later than 18 months after the
30 date of the enactment of this Act, the Comptroller General
31 shall submit to Congress a report on the study conducted
32 under paragraph (1). The report shall include a determina-
33 tion whether—

34 (A) data from claims submitted by physicians
35 under part B of the medicare program indicate poten-
36 tial access problems for medicare beneficiaries in cer-
37 tain geographic areas; and

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1 (B) access by medicare beneficiaries to physicians'
2 services may have improved, remained constant, or de-
3 teriorated over time.

4 (b) STUDY AND REPORT ON SUPPLY OF PHYSICIANS.—

5 (1) STUDY.—The Secretary shall request the Institute
6 of Medicine of the National Academy of Sciences to con-
7 duct a study on the adequacy of the supply of physicians
8 (including specialists) in the United States and the factors
9 that affect such supply.

10 (2) REPORT TO CONGRESS.—Not later than 2 years
11 after the date of enactment of this section, the Secretary
12 shall submit to Congress a report on the results of the
13 study described in paragraph (1), including any rec-
14 ommendations for legislation.

15 (c) GAO STUDY OF MEDICARE PAYMENT FOR INHALA-
16 TION THERAPY.—

17 (1) STUDY.—The Comptroller General of the United
18 States shall conduct a study to examine the adequacy of
19 current reimbursements for inhalation therapy under the
20 medicare program.

21 (2) REPORT.—Not later than May 1, 2004, the Comp-
22 troller General shall submit to Congress a report on the
23 study conducted under paragraph (1).

24 **SEC. 603. MEDPAC REPORT ON PAYMENT FOR PHYSI-**
25 **CIAANS' SERVICES.**

26 (a) PRACTICE EXPENSE COMPONENT.—Not later than 1
27 year after the date of the enactment of this Act, the Medicare
28 Payment Advisory Commission shall submit to Congress a re-
29 port on the effect of refinements to the practice expense compo-
30 nent of payments for physicians' services, after the transition
31 to a full resource-based payment system in 2002, under section
32 1848 of the Social Security Act (42 U.S.C. 1395w-4). Such re-
33 port shall examine the following matters by physician specialty:

34 (1) The effect of such refinements on payment for
35 physicians' services.

1 (2) The interaction of the practice expense component
2 with other components of and adjustments to payment for
3 physicians' services under such section.

4 (3) The appropriateness of the amount of compensa-
5 tion by reason of such refinements.

6 (4) The effect of such refinements on access to care
7 by medicare beneficiaries to physicians' services.

8 (5) The effect of such refinements on physician par-
9 ticipation under the medicare program.

10 (b) VOLUME OF PHYSICIAN SERVICES.—The Medicare
11 Payment Advisory Commission shall submit to Congress a re-
12 port on the extent to which increases in the volume of physi-
13 cians' services under part B of the medicare program are a re-
14 sult of care that improves the health and well-being of medicare
15 beneficiaries. The study shall include the following:

16 (1) An analysis of recent and historic growth in the
17 components that the Secretary includes under the sustain-
18 able growth rate (under section 1848(f) of the Social Secu-
19 rity Act).

20 (2) An examination of the relative growth of volume
21 in physician services between medicare beneficiaries and
22 other populations.

23 (3) An analysis of the degree to which new technology,
24 including coverage determinations of the Centers for Medi-
25 care & Medicaid Services, has affected the volume of physi-
26 cians' services.

27 (4) An examination of the impact on volume of demo-
28 graphic changes.

29 (5) An examination of shifts in the site of service of
30 services that influence the number and intensity of services
31 furnished in physicians' offices and the extent to which
32 changes in reimbursement rates to other providers have af-
33 fected these changes.

34 (6) An evaluation of the extent to which the Centers
35 for Medicare & Medicaid Services takes into account the
36 impact of law and regulations on the sustainable growth
37 rate.

1 **SEC. 604. INCLUSION OF PODIATRISTS UNDER PRIVATE**
2 **CONTRACTING AUTHORITY.**

3 Section 1802(b)(5)(B) (42 U.S.C. 1395a(b)(5)(B)) is
4 amended by striking “section 1861(r)(1)” and inserting “para-
5 graphs (1) and (3) or section 1861(r)”.

6 **Subtitle B—Preventive Services**

7 **SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYS-**
8 **ICAL EXAMINATION.**

9 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
10 1395x(s)(2)) is amended—

11 (1) in subparagraph (U), by striking “and” at the
12 end;

13 (2) in subparagraph (V), by inserting “and” at the
14 end; and

15 (3) by adding at the end the following new subpara-
16 graph:

17 “(W) an initial preventive physical examination (as de-
18 fined in subsection (ww));”.

19 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
20 1395x) is amended by adding at the end the following new sub-
21 section:

22 “Initial Preventive Physical Examination

23 “(ww) The term ‘initial preventive physical examination’
24 means physicians’ services consisting of a physical examination
25 with the goal of health promotion and disease detection and in-
26 cludes items and services (excluding clinical laboratory tests),
27 as determined by the Secretary, consistent with the rec-
28 ommendations of the United States Preventive Services Task
29 Force.”.

30 (c) WAIVER OF DEDUCTIBLE AND COINSURANCE.—

31 (1) DEDUCTIBLE.—The first sentence of section
32 1833(b) (42 U.S.C. 1395l(b)) is amended—

33 (A) by striking “and” before “(6)”, and

34 (B) by inserting before the period at the end the
35 following: “, and (7) such deductible shall not apply
36 with respect to an initial preventive physical examina-
37 tion (as defined in section 1861(ww))”.

1 (2) COINSURANCE.—Section 1833(a)(1) (42 U.S.C.
2 1395l(a)(1)) is amended—

3 (A) in clause (N), by inserting “(or 100 percent
4 in the case of an initial preventive physical examina-
5 tion, as defined in section 1861(w))” after “80 per-
6 cent”; and

7 (B) in clause (O), by inserting “(or 100 percent
8 in the case of an initial preventive physical examina-
9 tion, as defined in section 1861(w))” after “80 per-
10 cent”.

11 (d) PAYMENT AS PHYSICIANS’ SERVICES.—Section
12 1848(j)(3) (42 U.S.C. 1395w-4(j)(3)) is amended by inserting
13 “(2)(W),” after “(2)(S),”.

14 (e) OTHER CONFORMING AMENDMENTS.—Section 1862(a)
15 (42 U.S.C. 1395y(a)) is amended—

16 (1) in paragraph (1)—

17 (A) by striking “and” at the end of subparagraph
18 (H);

19 (B) by striking the semicolon at the end of sub-
20 paragraph (I) and inserting “, and”; and

21 (C) by adding at the end the following new sub-
22 paragraph:

23 “(J) in the case of an initial preventive physical exam-
24 ination, which is performed not later than 6 months after
25 the date the individual’s first coverage period begins under
26 part B;” and

27 (2) in paragraph (7), by striking “or (H)” and insert-
28 ing “(H), or (J)”.

29 (f) EFFECTIVE DATE.—The amendments made by this
30 section shall apply to services furnished on or after January 1,
31 2004, but only for individuals whose coverage period begins on
32 or after such date.

33 **SEC. 612. COVERAGE OF CHOLESTEROL AND BLOOD**
34 **LIPID SCREENING.**

35 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
36 1395x(s)(2)), as amended by section 611(a), is amended—

37 (1) in subparagraph (V), by striking “and” at the end;

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1 (2) in subparagraph (W), by inserting “and” at the
2 end; and

3 (3) by adding at the end the following new subpara-
4 graph:

5 “(X) cholesterol and other blood lipid screening
6 tests (as defined in subsection (XX));”.

7 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
8 1395x), as amended by section 611(b), is amended by adding
9 at the end the following new subsection:

10 “Cholesterol and Other Blood Lipid Screening Test

11 “(xx)(1) The term ‘cholesterol and other blood lipid
12 screening test’ means diagnostic testing of cholesterol and other
13 lipid levels of the blood for the purpose of early detection of
14 abnormal cholesterol and other lipid levels.

15 “(2) The Secretary shall establish standards, in consulta-
16 tion with appropriate organizations, regarding the frequency
17 and type of cholesterol and other blood lipid screening tests, ex-
18 cept that such frequency may not be more often than once
19 every 2 years.”.

20 (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.
21 1395y(a)(1)), as amended by section 611(e), is amended—

22 (1) by striking “and” at the end of subparagraph (I);

23 (2) by striking the semicolon at the end of subpara-
24 graph (J) and inserting “; and”; and

25 (3) by adding at the end the following new subpara-
26 graph:

27 “(K) in the case of a cholesterol and other blood lipid
28 screening test (as defined in section 1861(xx)(1)), which is
29 performed more frequently than is covered under section
30 1861(xx)(2).”.

31 (d) EFFECTIVE DATE.—The amendments made by this
32 section shall apply to tests furnished on or after January 1,
33 2005.

1 **SEC. 613. WAIVER OF DEDUCTIBLE FOR COLORECTAL**
2 **CANCER SCREENING TESTS.**

3 (a) IN GENERAL.—The first sentence of section 1833(b)
4 (42 U.S.C. 1395l(b)), as amended by section 611(c)(1), is
5 amended—

6 (1) by striking “and” before “(7)”; and

7 (2) by inserting before the period at the end the fol-
8 lowing: “, and (8) such deductible shall not apply with re-
9 spect to colorectal cancer screening tests (as described in
10 section 1861(pp)(1))”.

11 (b) CONFORMING AMENDMENTS.—Paragraphs (2)(C)(ii)
12 and (3)(C)(ii) of section 1834(d) (42 U.S.C. 1395m(d)) are
13 each amended—

14 (1) by striking “DEDUCTIBLE AND” in the heading;
15 and

16 (2) in subclause (I), by striking “deductible or” each
17 place it appears.

18 (c) EFFECTIVE DATE.—The amendment made by this sec-
19 tion shall apply to items and services furnished on or after
20 January 1, 2004.

21 **SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOG-**
22 **RAPHY SERVICES.**

23 (a) EXCLUSION FROM OPD FEE SCHEDULE.—Section
24 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by
25 inserting before the period at the end the following: “and does
26 not include screening mammography (as defined in section
27 1861(jj)) and unilateral and bilateral diagnostic mammog-
28 raphy”.

29 (b) ADJUSTMENT TO TECHNICAL COMPONENT.—For diag-
30 nostic mammography performed on or after January 1, 2004,
31 for which payment is made under the physician fee schedule
32 under section 1848 of the Social Security Act (42 U.S.C.
33 1395w-4), the Secretary, based on the most recent cost data
34 available, shall provide for an appropriate adjustment in the
35 payment amount for the technical component of the diagnostic
36 mammography.

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to mammography performed on or after January 1, 2004.

Subtitle C—Other Services

SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT REFORM.

(a) PAYMENT FOR DRUGS.—

(1) MODIFICATION OF AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS.—Section 1833(t) (42 U.S.C. 1395l(t)) is amended—

(A) by redesignating paragraph (13) as paragraph (14); and

(B) by inserting after paragraph (12) the following new paragraph:

“(13) DRUG APC PAYMENT RATES.—

“(A) IN GENERAL.—With respect to payment for covered OPD services that includes a specified covered outpatient drug (defined in subparagraph (B)), the amount provided for payment for such drug under the payment system under this subsection for services furnished in—

“(i) 2004, 2005, or 2006, shall in no case—

“(I) exceed 95 percent of the average wholesale price for the drug; or

“(II) be less than the transition percentage (under subparagraph (C)) of the average wholesale price for the drug; or

“(ii) a subsequent year, shall be equal to the average price for the drug for that area and year established under the competitive acquisition program under section 1847A as calculated and applied by the Secretary for purposes of this paragraph.

“(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

“(i) IN GENERAL.—In this paragraph, the term ‘specified covered outpatient drug’ means,

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subject to clause (ii), a covered outpatient drug (as defined in 1927(k)(2), that is—

“(I) a radiopharmaceutical; or

“(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

“(ii) EXCEPTION.—Such term does not include—

“(I) a drug for which payment is first made on or after January 1, 2003, under paragraph (6); or

“(II) a drug for a which a temporary HCPCS code has not been assigned.

“(C) TRANSITION TOWARDS HISTORICAL AVERAGE ACQUISITION COST.—The transition percentage under this subparagraph for drugs furnished in a year is determined in accordance with the following table:

The transition percentage for—

For the year—	Single source drugs are—	Innovator multiple source drugs are—	Generic drugs are—
2004	83%	81.5%	46%
2005	77%	75%	46%
2006	71%	68%	46%

“(D) PAYMENT FOR NEW DRUGS UNTIL TEMPORARY HCPCS CODE ASSIGNED.—With respect to payment for covered OPD services that includes a covered outpatient drug (as defined in 1927(k)) for a which a temporary HCPCS code has not been assigned, the amount provided for payment for such drug under the payment system under this subsection shall be equal to 95 percent of the average wholesale price for the drug.

“(E) CLASSES OF DRUGS.—For purposes of this paragraph, each of the following shall be treated as a separate class of drugs:

1 “(i) SOLE SOURCE DRUGS.—A sole source
2 drug which for purposes of this paragraph means
3 a drug or biological that is not a multiple source
4 drug (as defined in subclauses (I) and (II) of sec-
5 tion 1927(k)(7)(A)(i)) and is not a drug approved
6 under an abbreviated new drug application under
7 section 355(j) of the Federal Food, Drug, and Cos-
8 metic Act.

9 “(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—
10 Innovator multiple source drugs (as defined in sec-
11 tion 1927(k)(7)(A)(ii)).

12 “(iii) NONINNOVATOR MULTIPLE SOURCE
13 DRUGS.—Noninnovator multiple source drugs (as
14 defined in section 1927(k)(7)(A)(iii)).

15 “(F) INAPPLICABILITY OF EXPENDITURES IN DE-
16 TERMINING CONVERSION FACTORS.—Additional ex-
17 penditures resulting from this paragraph and para-
18 graph (14)(C) in a year shall not be taken into account
19 in establishing the conversion factor for that year.”.

20 (2) REDUCTION IN THRESHOLD FOR SEPARATE APCS
21 FOR DRUGS.—Section 1833(t)(14), as redesignated by
22 paragraph (1)(A), is amended by adding at the end the fol-
23 lowing new subparagraph:

24 “(B) THRESHOLD FOR ESTABLISHMENT OF SEPA-
25 RATE APCS FOR DRUGS.—The Secretary shall reduce
26 the threshold for the establishment of separate ambula-
27 tory procedure classification groups (APCs) with re-
28 spect to drugs to \$50 per administration.”.

29 (3) EXCLUSION OF SEPARATE DRUG APCS FROM
30 OUTLIER PAYMENTS.—Section 1833(t)(5) is amended by
31 adding at the end the following new subparagraph:

32 “(E) EXCLUSION OF SEPARATE DRUG APCS FROM
33 OUTLIER PAYMENTS.—No additional payment shall be
34 made under subparagraph (A) in the case of ambula-
35 tory procedure codes established separately for drugs.”.

36 (4) PAYMENT FOR PASS THROUGH DRUGS.—Clause (i)
37 of section 1833(t)(6)(D) (42 U.S.C. 1395l(t)(6)(D)) is

1 amended by inserting after “under section 1842(o)” the
2 following: “(or if the drug is covered under a competitive
3 acquisition contract under section 1847A for an area, an
4 amount determined by the Secretary equal to the average
5 price for the drug for that area and year established under
6 such section as calculated and applied by the Secretary for
7 purposes of this paragraph)”.

8 (5) EFFECTIVE DATE.—The amendments made by
9 this subsection shall apply to services furnished on or after
10 January 1, 2004.

11 (b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—

12 (1) IN GENERAL.—Section 1833(t)(14), as so redesign-
13 ated and amended by subsection (a)(2), is amended by
14 adding at the end the following new subparagraph:

15 “(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY
16 AT CHARGES ADJUSTED TO COST.—Notwithstanding
17 the preceding provisions of this subsection, for a device
18 of brachytherapy furnished on or after January 1,
19 2004, and before January 1, 2007, the payment basis
20 for the device under this subsection shall be equal to
21 the hospital’s charges for each device furnished, ad-
22 justed to cost.”.

23 (2) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY
24 DEVICES.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2) is
25 amended—

26 (A) in subparagraph (F), by striking “and” at the
27 end;

28 (B) in subparagraph (G), by striking the period at
29 the end and inserting “; and”; and

30 (C) by adding at the end the following new sub-
31 paragraph:

32 “(H) with respect to devices of brachytherapy, the
33 Secretary shall create additional groups of covered
34 OPD services that classify such devices separately from
35 the other services (or group of services) paid for under
36 this subsection in a manner reflecting the number, iso-
37 tope, and radioactive intensity of such devices fur-

nished, including separate groups for palladium-103 and iodine-125 devices.”.

(3) GAO REPORT.—The Comptroller General of the United States shall conduct a study to determine appropriate payment amounts under section 1833(t)(13)(B) of the Social Security Act, as added by paragraph (1), for devices of brachytherapy. Not later than January 1, 2005, the Comptroller General shall submit to Congress and the Secretary a report on the study conducted under this paragraph, and shall include specific recommendations for appropriate payments for such devices.

(c) APPLICATION OF FUNCTIONAL EQUIVALENCE TEST.—

(1) IN GENERAL.—Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new subparagraph:

“(F) LIMITATION ON APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—The Secretary may not apply a ‘functional equivalence’ payment standard (including such standard promulgated on November 1, 2002) or any other similar standard in order to deem a particular drug or biological to be identical to or similar to another drug or biological with respect to its mechanism of action or clinical effect to deny pass-through status to new drugs or biologics or to remove such status of an existing eligible drug or biologic under this paragraph unless—

“(i) the Secretary develops by regulation (after providing notice and a period for public comment) criteria for the application of such standard; and

“(ii) such criteria provide for coordination with the Federal Food and Drug Administration and require scientific studies that show the clinical relationship between the drugs or biologicals treated as functionally equivalent.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to the application of a functional equivalence standard to a drug or biological on or after the

1 date of the enactment of this Act, unless such application
2 was being made to such drug or biological prior to June
3 13, 2003.

4 (d) HOSPITAL ACQUISITION COST STUDY.—

5 (1) IN GENERAL.—The Secretary shall conduct a
6 study on the costs incurred by hospitals in acquiring cov-
7 ered outpatient drugs for which payment is made under
8 section 1833(t) of the Social Security Act (42 U.S.C.
9 1395l(t)).

10 (2) DRUGS COVERED.—The study in paragraph (1)
11 shall not include those drugs for which the acquisition costs
12 is less than \$50 per administration.

13 (3) REPRESENTATIVE SAMPLE OF HOSPITALS.—In
14 conducting the study under paragraph (1), the Secretary
15 shall collect data from a statistically valid sample of hos-
16 pitals with an urban/rural stratification.

17 (4) REPORT.—Not later than January 1, 2006, the
18 Secretary shall submit to Congress a report on the study
19 conducted under paragraph (1), and shall include rec-
20 ommendations with respect to the following:

21 (A) Whether the study should be repeated, and if
22 so, how frequently.

23 (B) Whether the study produced useful data on
24 hospital acquisition cost.

25 (C) Whether data produced in the study is appro-
26 priate for use in making adjustments to payments for
27 drugs and biologicals under section 1847A of the Social
28 Security Act.

29 (D) Whether separate estimates can made of over-
30 head costs, including handling and administering costs
31 for drugs.

32 **SEC. 622. PAYMENT FOR AMBULANCE SERVICES.**

33 (a) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE
34 SCHEDULE AND REGIONAL FEE SCHEDULES.—Section 1834(l)
35 (42 U.S.C. 1395m(l)), as amended by section 410(a), is
36 amended—

1 (1) in paragraph (2)(E), by inserting “consistent with
2 paragraph (11)” after “in an efficient and fair manner”;
3 and

4 (2) by adding at the end the following new paragraph:

5 “(11) PHASE-IN PROVIDING FLOOR USING BLEND OF
6 FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In car-
7 rying out the phase-in under paragraph (2)(E) for each
8 level of service furnished in a year, the portion of the pay-
9 ment amount that is based on the fee schedule shall be the
10 greater of the amount determined under such fee schedule
11 (without regard to this paragraph) or the following blended
12 rate of the fee schedule under paragraph (1) and of a re-
13 gional fee schedule for the region involved:

14 “(A) For 2004, the blended rate shall be based 20
15 percent on the fee schedule under paragraph (1) and
16 80 percent on the regional fee schedule.

17 “(B) For 2005, the blended rate shall be based 40
18 percent on the fee schedule under paragraph (1) and
19 60 percent on the regional fee schedule.

20 “(C) For 2006, the blended rate shall be based 60
21 percent on the fee schedule under paragraph (1) and
22 40 percent on the regional fee schedule.

23 “(D) For 2007, 2008, and 2009, the blended rate
24 shall be based 80 percent on the fee schedule under
25 paragraph (1) and 20 percent on the regional fee
26 schedule.

27 “(E) For 2010 and each succeeding year, the
28 blended rate shall be based 100 percent on the fee
29 schedule under paragraph (1).

30 For purposes of this paragraph, the Secretary shall estab-
31 lish a regional fee schedule for each of the 9 Census divi-
32 sions using the methodology (used in establishing the fee
33 schedule under paragraph (1)) to calculate a regional con-
34 version factor and a regional mileage payment rate and
35 using the same payment adjustments and the same relative
36 value units as used in the fee schedule under such para-
37 graph.”.

1 (b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG
2 TRIPS.—Section 1834(l), as amended by subsection (a), is fur-
3 ther amended by adding at the end the following new para-
4 graph:

5 “(12) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG
6 TRIPS.—In the case of ground ambulance services fur-
7 nished on or after January 1, 2004, and before January 1,
8 2009, regardless of where the transportation originates, the
9 fee schedule established under this subsection shall provide
10 that, with respect to the payment rate for mileage for a
11 trip above 50 miles the per mile rate otherwise established
12 shall be increased by $\frac{1}{4}$ of the payment per mile otherwise
13 applicable to such miles.”.

14 (c) GAO REPORT ON COSTS AND ACCESS.—Not later than
15 December 31, 2005, the Comptroller General of the United
16 States shall submit to Congress an initial report on how costs
17 differ among the types of ambulance providers and on access,
18 supply, and quality of ambulance services in those regions and
19 States that have a reduction in payment under the medicare
20 ambulance fee schedule (under section 1834(l) of the Social Se-
21 curity Act, as amended by this section). Not later than Decem-
22 ber 31, 2007, the Comptroller General shall submit to Congress
23 a final report on such access and supply.

24 (d) EFFECTIVE DATE.—The amendments made by this
25 section shall apply to ambulance services furnished on or after
26 January 1, 2004.

27 **SEC. 623. RENAL DIALYSIS SERVICES.**

28 (a) DEMONSTRATION OF ALTERNATIVE DELIVERY MOD-
29 ELS.—

30 (1) USE OF ADVISORY BOARD.—In carrying out the
31 demonstration project relating to improving care for people
32 with end-stage renal disease through alternative delivery
33 models (as published in the Federal Register of June 4,
34 2003), the Secretary shall establish an advisory board com-
35 prised of representatives described in paragraph (2) to pro-
36 vide advice and recommendations with respect to the estab-
37 lishment and operation of such demonstration project.

1 (2) REPRESENTATIVES.—Representatives referred to
2 in paragraph (1) include representatives of the following:

3 (A) Patient organizations.

4 (B) Clinicians.

5 (C) The medicare payment advisory commission,
6 established under section 1805 of the Social Security
7 Act (42 U.S.C. 1395b–6).

8 (D) The National Kidney Foundation.

9 (E) The National Institute of Diabetes and Diges-
10 tive and Kidney Diseases of National Institutes of
11 Health.

12 (F) End-stage renal disease networks.

13 (G) Medicare contractors to monitor quality of
14 care.

15 (I) providers of services and renal dialysis facilities
16 furnishing end-stage renal disease services.

17 (J) Economists.

18 (K) Researchers.

19 (b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDI-
20 ATRIC FACILITIES.—

21 (1) IN GENERAL.—Section 422(a)(2) of BIPA is
22 amended—

23 (A) in subparagraph (A), by striking “and (C)”
24 and inserting “, (C), and (D)”;

25 (B) in subparagraph (B), by striking “In the
26 case” and inserting “Subject to subparagraph (D), in
27 the case”; and

28 (C) by adding at the end the following new sub-
29 paragraph:

30 “(D) INAPPLICABILITY TO PEDIATRIC FACILI-
31 TIES.—Subparagraphs (A) and (B) shall not apply, as
32 of October 1, 2002, to pediatric facilities that do not
33 have an exception rate described in subparagraph (C)
34 in effect on such date. For purposes of this subpara-
35 graph, the term ‘pediatric facility’ means a renal facil-
36 ity at least 50 percent of whose patients are individuals
37 under 18 years of age.”.

1 (2) CONFORMING AMENDMENT.—The fourth sentence
2 of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)), as amend-
3 ed by subsection (b), is further amended by striking
4 “Until” and inserting “Subject to section 422(a)(2) of the
5 Medicare, Medicaid, and SCHIP Benefits Improvement and
6 Protection Act of 2000, and until”.

7 (c) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR
8 SERVICES FURNISHED IN 2004.—Notwithstanding any other
9 provision of law, with respect to payment under part B of title
10 XVIII of the Social Security Act for renal dialysis services fur-
11 nished in 2004, the composite payment rate otherwise estab-
12 lished under section 1881(b)(7) of such Act (42 U.S.C.
13 1395rr(b)(7)) shall be increased by 1.6 percent.

14 **SEC. 624. ONE-YEAR MORATORIUM ON THERAPY CAPS;**
15 **PROVISIONS RELATING TO REPORTS.**

16 (a) 1-YEAR MORATORIUM ON THERAPY CAPS.—Section
17 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by striking
18 “and 2002” and inserting “2002, and 2004”.

19 (b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAY-
20 MENT AND UTILIZATION OF OUTPATIENT THERAPY SERV-
21 ICES.—Not later than December 31, 2003, the Secretary shall
22 submit to Congress the reports required under section
23 4541(d)(2) of the Balanced Budget Act of 1997 (relating to al-
24 ternatives to a single annual dollar cap on outpatient therapy)
25 and under section 221(d) of the Medicare, Medicaid, and
26 SCHIP Balanced Budget Refinement Act of 1999 (relating to
27 utilization patterns for outpatient therapy).

28 (c) IDENTIFICATION OF CONDITIONS AND DISEASES JUS-
29 TIFYING WAIVER OF THERAPY CAP.—

30 (1) STUDY.—The Secretary shall request the Institute
31 of Medicine of the National Academy of Sciences to identify
32 conditions or diseases that should justify conducting an as-
33 sessment of the need to waive the therapy caps under sec-
34 tion 1833(g)(4) of the Social Security Act (42 U.S.C.
35 1395l(g)(4)).

36 (2) REPORTS TO CONGRESS.—

220

1 (A) PRELIMINARY REPORT.—Not later than July
2 1, 2004, the Secretary shall submit to Congress a pre-
3 liminary report on the conditions and diseases identi-
4 fied under paragraph (1).

5 (B) FINAL REPORT.—Not later than September 1,
6 2004, the Secretary shall submit to Congress a final re-
7 port on such conditions and diseases.

8 (C) RECOMMENDATIONS.—Not later than October
9 1, 2004, the Secretary shall submit to Congress a rec-
10 ommendation of criteria, with respect to such condi-
11 tions and disease, under which a waiver of the therapy
12 caps would apply.

13 (d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL
14 THERAPIST SERVICES.—

15 (1) STUDY.—The Comptroller General of the United
16 States shall conduct a study on access to physical therapist
17 services in States authorizing such services without a physi-
18 cian referral and in States that require such a physician re-
19 ferral. The study shall—

20 (A) examine the use of and referral patterns for
21 physical therapist services for patients age 50 and older
22 in States that authorize such services without a physi-
23 cian referral and in States that require such a physi-
24 cian referral;

25 (B) examine the use of and referral patterns for
26 physical therapist services for patients who are medi-
27 care beneficiaries;

28 (C) examine the potential effect of prohibiting a
29 physician from referring patients to physical therapy
30 services owned by the physician and provided in the
31 physician's office;

32 (D) examine the delivery of physical therapists'
33 services within the facilities of Department of Defense;
34 and

35 (E) analyze the potential impact on medicare
36 beneficiaries and on expenditures under the medicare
37 program of eliminating the need for a physician refer-

1 ral and physician certification for physical therapist
2 services under the medicare program.

3 (2) REPORT.—The Comptroller General shall submit
4 to Congress a report on the study conducted under para-
5 graph (1) by not later than 1 year after the date of the
6 enactment of this Act.

7 **SEC. 625. ADJUSTMENT TO PAYMENTS FOR SERVICES**
8 **FURNISHED IN AMBULATORY SURGICAL**
9 **CENTERS.**

10 Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is
11 amended in the last sentence by inserting “and each of fiscal
12 years 2004 through 2008” after “In each of the fiscal years
13 1998 through 2002”.

14 **SEC. 626. PAYMENT FOR CERTAIN SHOES AND INSERTS**
15 **UNDER THE FEE SCHEDULE FOR ORTHOTICS**
16 **AND PROSTHETICS.**

17 (a) IN GENERAL.—Section 1833(o) (42 U.S.C. 1395l(o))
18 is amended—

19 (1) in paragraph (1), by striking “no more than the
20 limits established under paragraph (2)” and inserting “no
21 more than the amount of payment applicable under para-
22 graph (2)”;

23 (2) in paragraph (2), to read as follows:

24 “(2)(A) Except as provided by the Secretary under sub-
25 paragraphs (B) and (C), the amount of payment under this
26 paragraph for custom molded shoes, extra depth shoes, and in-
27 serts shall be the amount determined for such items by the
28 Secretary under section 1834(h).

29 “(B) The Secretary or a carrier may establish payment
30 amounts for shoes and inserts that are lower than the amount
31 established under section 1834(h) if the Secretary finds that
32 shoes and inserts of an appropriate quality are readily available
33 at or below the amount established under such section.

34 “(C) In accordance with procedures established by the
35 Secretary, an individual entitled to benefits with respect to
36 shoes described in section 1861(s)(12) may substitute modifica-
37 tion of such shoes instead of obtaining one (or more, as speci-
38 fied by the Secretary) pair of inserts (other than the original

1 pair of inserts with respect to such shoes). In such case, the
2 Secretary shall substitute, for the payment amount established
3 under section 1834(h), a payment amount that the Secretary
4 estimates will assure that there is no net increase in expendi-
5 tures under this subsection as a result of this subparagraph.”.

6 (b) CONFORMING AMENDMENTS.—(1) Section
7 1834(h)(4)(C) (42 U.S.C. 1395m(h)(4)(C)) is amended by in-
8 serting “(and includes shoes described in section 1861(s)(12))”
9 after “in section 1861(s)(9)”.

10 (2) Section 1842(s)(2) (42 U.S.C. 1395u(s)(2)) is amend-
11 ed by striking subparagraph (C).

12 (c) EFFECTIVE DATE.—The amendments made by this
13 section shall apply to items furnished on or after January 1,
14 2004.

15 **SEC. 627. WAIVER OF PART B LATE ENROLLMENT PEN-**
16 **ALTY FOR CERTAIN MILITARY RETIREES;**
17 **SPECIAL ENROLLMENT PERIOD.**

18 (a) WAIVER OF PENALTY.—

19 (1) IN GENERAL.—Section 1839(b) (42 U.S.C.
20 1395r(b)) is amended by adding at the end the following
21 new sentence: “No increase in the premium shall be ef-
22 fected for a month in the case of an individual who is 65
23 years of age or older, who enrolls under this part during
24 2001, 2002, 2003, or 2004 and who demonstrates to the
25 Secretary before December 31, 2004, that the individual is
26 a covered beneficiary (as defined in section 1072(5) of title
27 10, United States Code). The Secretary of Health and
28 Human Services shall consult with the Secretary of De-
29 fense in identifying individuals described in the previous
30 sentence.”.

31 (2) EFFECTIVE DATE.—The amendment made by
32 paragraph (1) shall apply to premiums for months begin-
33 ning with January 2003. The Secretary of Health and
34 Human Services shall establish a method for providing re-
35 bates of premium penalties paid for months on or after
36 January 2004 for which a penalty does not apply under

1 such amendment but for which a penalty was previously
2 collected.

3 (b) MEDICARE PART B SPECIAL ENROLLMENT PERIOD.—

4 (1) IN GENERAL.—In the case of any individual who,
5 as of the date of the enactment of this Act, is 65 years of
6 age or older, is eligible to enroll but is not enrolled under
7 part B of title XVIII of the Social Security Act, and is a
8 covered beneficiary (as defined in section 1072(5) of title
9 10, United States Code), the Secretary of Health and
10 Human Services shall provide for a special enrollment pe-
11 riod during which the individual may enroll under such
12 part. Such period shall begin as soon as possible after the
13 date of the enactment of this Act and shall end on Decem-
14 ber 31, 2004.

15 (2) COVERAGE PERIOD.—In the case of an individual
16 who enrolls during the special enrollment period provided
17 under paragraph (1), the coverage period under part B of
18 title XVIII of the Social Security Act shall begin on the
19 first day of the month following the month in which the in-
20 dividual enrolls.

21 **SEC. 628. PART B DEDUCTIBLE.**

22 Section 1833(b) (42 U.S.C. 1395l(b)) is amended—

23 (1) by striking “1991 and” and inserting “1991,”;
24 and

25 (2) by striking “and subsequent years” and inserting
26 “and each subsequent year through 2003, and for a subse-
27 quent year after 2003 the amount of such deductible for
28 the previous year increased by the annual percentage in-
29 crease in the monthly actuarial rate under section
30 1839(a)(1) ending with such subsequent year (rounded to
31 the nearest \$1)”.

32 **TITLE VII—PROVISIONS RELATING**
33 **TO PARTS A AND B**
34 **Subtitle A—Home Health Services**

35 **SEC. 701. UPDATE IN HOME HEALTH SERVICES.**

36 (a) CHANGE TO CALENDER YEAR UPDATE.—

1 (1) IN GENERAL.—Section 1895(b) (42 U.S.C.
2 1395fff(b)(3)) is amended—

3 (A) in paragraph (3)(B)(i)—

4 (i) by striking “each fiscal year (beginning
5 with fiscal year 2002)” and inserting “fiscal year
6 2002 and for fiscal year 2003 and for each subse-
7 quent year (beginning with 2004)”; and

8 (ii) by inserting “or year” after “the fiscal
9 year”;

10 (B) in paragraph (3)(B)(ii)(II), by striking “any
11 subsequent fiscal year” and inserting “2004 and any
12 subsequent year”;

13 (C) in paragraph (3)(B)(iii), by inserting “or
14 year” after “fiscal year” each place it appears;

15 (D) in paragraph (3)(B)(iv)—

16 (i) by inserting “or year” after “fiscal year”
17 each place it appears; and

18 (ii) by inserting “or years” after “fiscal
19 years”; and

20 (E) in paragraph (5), by inserting “or year” after
21 “fiscal year”.

22 (2) TRANSITION RULE.—The standard prospective
23 payment amount (or amounts) under section 1895(b)(3) of
24 the Social Security Act for the calendar quarter beginning
25 on October 1, 2003, shall be such amount (or amounts) for
26 the previous calendar quarter.

27 (b) CHANGES IN UPDATES FOR 2004, 2005, AND 2006.—
28 Section 1895(b)(3)(B)(ii) (42 U.S.C. 1395fff(b)(3)(B)(ii)), as
29 amended by subsection (a)(1)(B), is amended—

30 (1) by striking “or” at the end of subclause (I);

31 (2) by redesignating subclause (II) as subclause (III);

32 (3) in subclause (III), as so redesignated, by striking
33 “2004” and inserting “2007”; and

34 (4) by inserting after subclause (I) the following new
35 subclause:

1 “(II) each of 2004, 2005, and 2006 the
2 home health market basket percentage increase
3 minus 0.4 percentage points; or”.

4 **SEC. 702. ESTABLISHMENT OF REDUCED COPAYMENT**
5 **FOR A HOME HEALTH SERVICE EPISODE OF**
6 **CARE FOR CERTAIN BENEFICIARIES.**

7 (a) PART A.—

8 (1) IN GENERAL.—Section 1813(a) (42 U.S.C.
9 1395e(a)) is amended by adding at the end the following
10 new paragraph:

11 “(5)(A)(i) Subject to clause (ii), the amount payable for
12 home health services furnished to the individual under this title
13 for each episode of care beginning in a year (beginning with
14 2004) shall be reduced by a copayment equal to the copayment
15 amount specified in subparagraph (B)(ii) for such year.

16 “(ii) The copayment under clause (i) shall not apply—

17 “(I) in the case of an individual who has been deter-
18 mined to be entitled to medical assistance under section
19 1902(a)(10)(A) or 1902(a)(10)(C) or to be a qualified
20 medicare beneficiary (as defined in section 1905(p)(1)), a
21 specified low-income medicare beneficiary described in sec-
22 tion 1902(a)(10)(E)(iii), or a qualifying individual de-
23 scribed in section 1902(a)(10)(E)(iv)(I); and

24 “(II) in the case of an episode of care which consists
25 of 4 or fewer visits.

26 “(B)(i) The Secretary shall estimate, before the beginning
27 of each year (beginning with 2004), the national average pay-
28 ment under this title per episode for home health services pro-
29 jected for the year involved.

30 “(ii) For each year the copayment amount under this
31 clause is equal to 1.5 percent of the national average payment
32 estimated for the year involved under clause (i). Any amount
33 determined under the preceding sentence which is not a mul-
34 tiple of \$5 shall be rounded to the nearest multiple of \$5.

35 “(iii) There shall be no administrative or judicial review
36 under section 1869, 1878, or otherwise of the estimation of av-
37 erage payment under clause (i).”.

(2) TIMELY IMPLEMENTATION.—Unless the Secretary of Health and Human Services otherwise provides on a timely basis, the copayment amount specified under section 1813(a)(5)(B)(ii) of the Social Security Act (as added by paragraph (1)) for 2004 shall be deemed to be \$40.

(b) CONFORMING PROVISIONS.—

(1) Section 1833(a)(2)(A) (42 U.S.C. 1395l(a)(2)(A)) is amended by inserting “less the copayment amount applicable under section 1813(a)(5)” after “1895”.

(2) Section 1866(a)(2)(A)(i) (42 U.S.C. 1395cc(a)(2)(A)(i)) is amended—

(A) by striking “or coinsurance” and inserting “, coinsurance, or copayment”; and

(B) by striking “or (a)(4)” and inserting “(a)(4), or (a)(5)”.

SEC. 703. MEDPAC STUDY ON MEDICARE MARGINS OF HOME HEALTH AGENCIES.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of payment margins of home health agencies under the home health prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1395fff). Such study shall examine whether systematic differences in payment margins are related to differences in case mix (as measured by home health resource groups (HHRGs)) among such agencies. The study shall use the partial or full-year cost reports filed by home health agencies.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study under subsection (a).

Subtitle B—Direct Graduate Medical Education

SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH COST PROGRAMS.

Section 1886(h)(2)(D)(iv) (42 U.S.C. 1395ww(h)(2)(D)(iv)) is amended—

(1) in subclause (I)—

1 (A) by inserting “AND 2004 THROUGH 2013” after
2 “AND 2002”; and

3 (B) by inserting “or during the period beginning
4 with fiscal year 2004 and ending with fiscal year 2013”
5 after “during fiscal year 2001 or fiscal year 2002”;
6 and

7 (2) in subclause (II)—

8 (A) by striking “fiscal year 2004, or fiscal year
9 2005,” and

10 (B) by striking “For a” and inserting “For the”.

11 **Subtitle C—Chronic Care**
12 **Improvement**

13 **SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT**
14 **UNDER TRADITIONAL FEE-FOR-SERVICE.**

15 Title XVIII, as amended by section 105(a), is amended by
16 inserting after section 1807 the following new section:

17 “CHRONIC CARE IMPROVEMENT

18 “SEC. 1808. (a) IN GENERAL.—

19 “(1) IN GENERAL.—The Secretary shall establish a
20 process for providing chronic care improvement programs
21 in each CCIA region for medicare beneficiaries who are not
22 enrolled under part C or E and who have certain chronic
23 conditions, such as congestive heart failure, diabetes,
24 chronic obstructive pulmonary disease (COPD), stroke, or
25 other disease as identified by the Secretary as appropriate
26 for chronic care improvement. Such a process shall begin
27 to be implemented no later than 1 year after the date of
28 the enactment of this section.

29 “(2) TERMINOLOGY.—For purposes of this section:

30 “(A) CCIA REGION.—The term ‘CCIA region’
31 means a chronic care improvement administrative re-
32 gion delineated under subsection (b)(2).

33 “(B) CHRONIC CARE IMPROVEMENT PROGRAM.—
34 The terms ‘chronic care improvement program’ and
35 ‘program’ means such a program provided by a con-
36 tractor under this section.

1 “(C) CONTRACTOR.—The term ‘contractor’ means
2 an entity with a contract to provide a chronic care im-
3 provement program in a CCIA region under this sec-
4 tion.

5 “(D) INDIVIDUAL PLAN.—The term ‘individual
6 plan’ means a chronic care improvement plan estab-
7 lished under subsection (c)(5) for an individual.

8 “(3) CONSTRUCTION.—Nothing in this section shall be
9 construed as expanding the amount, duration, or scope of
10 benefits under this title.

11 “(b) COMPETITIVE BIDDING PROCESS.—

12 “(1) IN GENERAL.—Under this section the Secretary
13 shall award contracts to qualified entities for chronic care
14 improvement programs for each CCIA region under this
15 section through a competitive bidding process.

16 “(2) PROCESS.—Under such process—

17 “(A) the Secretary shall delineate the United
18 States into multiple chronic care improvement adminis-
19 trative regions; and

20 “(B) the Secretary shall select at least 2 winning
21 bidders in each CCIA region on the basis of the ability
22 of each bidder to carry out a chronic care improvement
23 program in accordance with this section, in order to
24 achieve improved health and financial outcomes.

25 “(3) ELIGIBLE CONTRACTOR.—A contractor may be a
26 disease improvement organization, health insurer, provider
27 organization, a group of physicians, or any other legal enti-
28 ty that the Secretary determines appropriate.

29 “(c) CHRONIC CARE IMPROVEMENT PROGRAMS.—

30 “(1) IN GENERAL.—Each contract under this section
31 shall provide for the operation of a chronic care improve-
32 ment program by a contractor in a CCIA region consistent
33 with this subsection.

34 “(2) IDENTIFICATION OF PROSPECTIVE PROGRAM PAR-
35 TICIPANTS.—Each contractor shall have a method for iden-
36 tifying medicare beneficiaries in the region to whom it will
37 offer services under its program. The contractor shall iden-

1 tify such beneficiaries through claims or other data and
2 other means permitted consistent with applicable disclosure
3 provisions.

4 “(3) INITIAL CONTACT BY SECRETARY.—The Sec-
5 retary shall communicate with each beneficiary identified
6 under paragraph (2) as a prospective participant in one or
7 more programs concerning participation in a program.
8 Such communication may be made by the Secretary (or on
9 behalf of the Secretary) and shall include information on
10 the following:

11 “(A) A description of the advantages to the bene-
12 ficiary in participating in a program.

13 “(B) Notification that the contractor offering a
14 program may contact the beneficiary directly con-
15 cerning such participation.

16 “(C) Notification that participation in a program
17 is voluntary.

18 “(D) A description of the method for the bene-
19 ficiary to select the single program in which the bene-
20 ficiary wishes to participate and for declining to partici-
21 pate and a method for obtaining additional information
22 concerning such participation.

23 “(4) PARTICIPATION.—A medicare beneficiary may
24 participate in only one program under this section and may
25 terminate participation at any time in a manner specified
26 by the Secretary.

27 “(5) INDIVIDUAL CHRONIC CARE IMPROVEMENT
28 PLANS.—

29 “(A) IN GENERAL.—For each beneficiary partici-
30 pating in a program of a contractor under this section,
31 the contractor shall develop with the beneficiary an in-
32 dividualized, goal-oriented chronic care improvement
33 plan.

34 “(B) ELEMENTS OF INDIVIDUAL PLAN.—Each in-
35 dividual plan developed under subparagraph (A) shall
36 include a single point of contact to coordinate care and
37 the following, as appropriate:

1 “(i) Self-improvement education for the bene-
2 ficiary and support education for health care pro-
3 viders, primary caregivers, and family members.

4 “(ii) Coordination of health care services, such
5 as application of a prescription drug regimen and
6 home health services.

7 “(iii) Collaboration with physicians and other
8 providers to enhance communication of relevant
9 clinical information.

10 “(iv) The use of monitoring technologies that
11 enable patient guidance through the exchange of
12 pertinent clinical information, such as vital signs,
13 symptomatic information, and health self-assess-
14 ment.

15 “(v) The provision of information about hos-
16 pice care, pain and palliative care, and end-of-life
17 care.

18 “(C) CONTRACTOR RESPONSIBILITIES.—In estab-
19 lishing and carrying out individual plans under a pro-
20 gram, a contractor shall, directly or through
21 subcontractors—

22 “(i) guide participants in managing their
23 health, including all their co-morbidities, and in
24 performing activities as specified under the ele-
25 ments of the plan;

26 “(ii) use decision support tools such as evi-
27 dence-based practice guidelines or other criteria as
28 determined by the Secretary; and

29 “(iii) develop a clinical information database
30 to track and monitor each participant across set-
31 tings and to evaluate outcomes.

32 “(6) ADDITIONAL REQUIREMENTS.—The Secretary
33 may establish additional requirements for programs and
34 contractors under this section.

35 “(7) ACCREDITATION.—The Secretary may provide
36 that programs that are accredited by qualified organiza-

1 tions may be deemed to meet such requirements under this
2 section as the Secretary may specify.

3 “(c) CONTRACT TERMS.—

4 “(1) IN GENERAL.—A contract under this section shall
5 contain such terms and conditions as the Secretary may
6 specify consistent with this section. The Secretary may not
7 enter into a contract with an entity under this section un-
8 less the entity meets such clinical, quality improvement, fi-
9 nancial, and other requirements as the Secretary deems to
10 be appropriate for the population to be served.

11 “(2) USE OF SUBCONTRACTORS PERMITTED.—A con-
12 tractor may carry out a program directly or through con-
13 tracts with subcontractors.

14 “(3) BUDGET NEUTRAL PAYMENT CONDITION.—In en-
15 tering into a contract with an entity under this subsection,
16 the Secretary shall establish payment rates that assure that
17 there will be no net aggregate increase in payments under
18 this title over any period of 3 years or longer, as agreed
19 to by the Secretary. Under this section, the Secretary shall
20 assure that medicare program outlays plus administrative
21 expenses (that would not have been paid under this title
22 without implementation of this section), including con-
23 tractor fees, shall not exceed the expenditures that would
24 have been incurred under this title for a comparable popu-
25 lation in the absence of the program under this section for
26 the 3-year contract period.

27 “(4) AT RISK RELATIONSHIP.—For purposes of sec-
28 tion 1128B(b)(3)(F), a contract under this section shall be
29 treated as a risk-sharing arrangement referred to in such
30 section.

31 “(5) PERFORMANCE STANDARDS.—Payment to con-
32 tractors under this section shall be subject to the contrac-
33 tor’s meeting of clinical and financial performance stand-
34 ards set by the Secretary.

35 “(6) CONTRACTOR OUTCOMES REPORT.—Each con-
36 tractor offering a program shall monitor and report to the

1 Secretary, in a manner specified by the Secretary, the qual-
2 ity of care and efficacy of such program in terms of—

3 “(A) process measures, such as reductions in er-
4 rors of treatment and rehospitalization rates;

5 “(B) beneficiary and provider satisfaction;

6 “(C) health outcomes; and

7 “(D) financial outcomes.

8 “(7) PHASED IN IMPLEMENTATION.—Nothing in this
9 section shall be construed as preventing the Secretary from
10 phasing in the implementation of programs.

11 “(d) BIENNIAL OUTCOMES REPORTS.—The Secretary
12 shall submit to the Congress biennial reports on the implemen-
13 tation of this section. Each such report shall include informa-
14 tion on—

15 “(1) the scope of implementation (in terms of both re-
16 gions and chronic conditions);

17 “(2) program design; and

18 “(3) improvements in health outcomes and financial
19 efficiencies that result from such implementation.

20 “(e) CLINICAL TRIALS.—The Secretary shall conduct ran-
21 domized clinical trials, that compare program participants with
22 medicare beneficiaries who are offered, but decline, to partici-
23 pate, in order to assess the potential of programs to—

24 “(1) reduce costs under this title; and

25 “(2) improve health outcomes under this title.

26 “(f) AUTHORIZATION OF APPROPRIATIONS.—There are
27 authorized to be appropriated to the Secretary, in appropriate
28 part from the Hospital Insurance Trust Fund and the Supple-
29 mentary Medical Insurance Trust Fund, such sums as may be
30 necessary to provide for contracts with chronic care improve-
31 ment programs under this section.

32 “(g) LIMITATION ON FUNDING.—In no case shall the
33 funding under this section exceed \$100,000,000 over a period
34 of 3 years.”.

SEC. 722. CHRONIC CARE IMPROVEMENT UNDER MEDICARE ADVANTAGE AND ENHANCED FEE-FOR-SERVICE PROGRAMS.

(a) UNDER MEDICARE ADVANTAGE PROGRAM.—Section 1852 (42 U.S.C. 1395w–22) is amended—

(1) by amending subsection (e) to read as follows:

“(e) IMPLEMENTATION OF CHRONIC CARE IMPROVEMENT PROGRAMS FOR BENEFICIARIES WITH MULTIPLE OR SUFFICIENTLY SEVERE CHRONIC CONDITIONS.—

“(1) IN GENERAL.—Each Medicare Advantage organization with respect to each Medicare Advantage plan it offers shall have in effect, for enrollees with multiple or sufficiently severe chronic conditions, a chronic care improvement program that is designed to manage the needs of such enrollees and that meets the requirements of this subsection.

“(2) ENROLLEE WITH MULTIPLE OR SUFFICIENTLY SEVERE CHRONIC CONDITIONS.—For purposes of this subsection, the term ‘enrollee with multiple or sufficiently severe chronic conditions’ means, with respect to an enrollee in a Medicare Advantage plan of a Medicare Advantage organization, an enrollee in the plan who has one or more chronic conditions, such as congestive heart failure, diabetes, COPD, stroke, or other disease as identified by the organization as appropriate for chronic care improvement.

“(3) GENERAL REQUIREMENTS.—

“(A) IN GENERAL.—Each chronic care improvement program under this subsection shall be conducted consistent with this subsection.

“(B) IDENTIFICATION OF ENROLLEES.—Each such program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet the organization’s criteria for participation under the program.

“(C) DEVELOPMENT OF PLANS.—For an enrollee identified under subparagraph (B) for participation in a program, the program shall develop, with the enroll-

1 ee's consent, an individualized, goal-oriented chronic
2 care improvement plan for chronic care improvement.

3 “(D) ELEMENTS OF PLANS.—Each chronic care
4 improvement plan developed under subparagraph (C)
5 shall include a single point of contact to coordinate
6 care and the following, as appropriate:

7 “(i) Self-improvement education for the en-
8 rollee and support education for health care pro-
9 viders, primary caregivers, and family members.

10 “(ii) Coordination of health care services, such
11 as application of a prescription drug regimen and
12 home health services.

13 “(iii) Collaboration with physicians and other
14 providers to enhance communication of relevant
15 clinical information.

16 “(iv) The use of monitoring technologies that
17 enable patient guidance through the exchange of
18 pertinent clinical information, such as vital signs,
19 symptomatic information, and health self-assess-
20 ment.

21 “(v) The provision of information about hos-
22 pice care, pain and palliative care, and end-of-life
23 care.

24 “(E) ORGANIZATION RESPONSIBILITIES.—In es-
25 tablishing and carrying out chronic care improvement
26 plans for participants under this paragraph, a Medicare
27 Advantage organization shall, directly or through
28 subcontractors—

29 “(i) guide participants in managing their
30 health, including all their co-morbidities, and in
31 performing the activities as specified under the ele-
32 ments of the plan;

33 “(ii) use decision support tools such as evi-
34 dence-based practice guidelines or other criteria as
35 determined by the Secretary; and

1 “(iii) develop a clinical information database
2 to track and monitor each participant across set-
3 tings and to evaluate outcomes.

4 “(3) ADDITIONAL REQUIREMENTS.—The Secretary
5 may establish additional requirements for chronic care im-
6 provement programs under this section.

7 “(4) ACCREDITATION.—The Secretary may provide
8 that chronic care improvement programs that are accred-
9 ited by qualified organizations may be deemed to meet such
10 requirements under this subsection as the Secretary may
11 specify.

12 “(5) OUTCOMES REPORT.—Each Medicare Advantage
13 organization with respect to its chronic care improvement
14 program under this subsection shall monitor and report to
15 the Secretary information on the quality of care and effi-
16 cacy of such program as the Secretary may require.”; and

17 (2) by amending subparagraph (I) of subsection (c)(1)
18 to read as follows:

19 “(I) CHRONIC CARE IMPROVEMENT PROGRAM.—A
20 description of the organization’s chronic care improve-
21 ment program under subsection (e).”.

22 (b) APPLICATION UNDER ENHANCED FEE-FOR-SERVICE
23 PROGRAM.—Section 1860E-2(c)(3), as inserted by section
24 201(a), is amended by inserting “, including subsection (e) (re-
25 lating to implementation of chronic care improvement pro-
26 grams)” after “The provisions of section 1852”.

27 (c) EFFECTIVE DATE.—The amendments made by this
28 section shall apply for contract years beginning on or after 1
29 year after the date of the enactment of this Act.

30 **SEC. 723. INSTITUTE OF MEDICINE REPORT.**

31 (a) STUDY.—

32 (1) IN GENERAL.—The Secretary of Health and
33 Human Services shall contract with the Institute of Medi-
34 cine of the National Academy of Sciences to conduct a
35 study of the barriers to effective integrated care improve-
36 ment for medicare beneficiaries with multiple or severe

1 chronic conditions across settings and over time and to
2 submit a report under subsection (b).

3 (2) SPECIFIC ITEMS.—The study shall examine the
4 statutory and regulatory barriers to coordinating care
5 across settings for medicare beneficiaries in transition from
6 one setting to another (such as between hospital, nursing
7 facility, home health, hospice, and home). The study shall
8 specifically identify the following:

9 (A) Clinical, financial, or administrative require-
10 ments in the medicare program that present barriers to
11 effective, seamless transitions across care settings.

12 (B) Policies that impede the establishment of ad-
13 ministrative and clinical information systems to track
14 health status, utilization, cost, and quality data across
15 settings.

16 (C) State-level requirements that may present bar-
17 riers to better care for medicare beneficiaries.

18 (3) CONSULTATION.—The study under this subsection
19 shall be conducted in consultation with experts in the field
20 of chronic care, consumers, and family caregivers, working
21 to integrate care delivery and create more seamless transi-
22 tions across settings and over time.

23 (b) REPORT.—The report under this subsection shall be
24 submitted to the Secretary and Congress not later than 18
25 months after the date of the enactment of this Act.

26 **SEC. 724. MEDPAC REPORT.**

27 (a) EVALUATION.—shall conduct an evaluation that in-
28 cludes a description of the status of the implementation of
29 chronic care improvement programs under section 1808 of the
30 Social Security Act, the quality of health care services provided
31 to individuals in such program, the health status of the partici-
32 pants of such program, and the cost savings attributed to im-
33 plementation of such program.

34 (b) REPORT.—Not later than 2 years after the date of im-
35 plementation of such chronic care improvement programs, the
36 Commission shall submit a report on such evaluation.

Subtitle D—Other Provisions

SEC. 731. MODIFICATIONS TO MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXAMINATION OF BUDGET CONSEQUENCES.—Section 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the end the following new paragraph:

“(8) EXAMINATION OF BUDGET CONSEQUENCES.—Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities.”.

(b) CONSIDERATION OF EFFICIENT PROVISION OF SERVICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–6(b)(2)(B)(i)) is amended by inserting “the efficient provision of” after “expenditures for”.

(c) APPLICATION OF DISCLOSURE REQUIREMENTS.—

(1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C. 1395b–6(c)(2)(D)) is amended by adding at the end the following: “Members of the Commission shall be treated as employees of the Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95–521).”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on January 1, 2004.

(d) ADDITIONAL REPORTS.—

(1) DATA NEEDS AND SOURCES.—The Medicare Payment Advisory Commission shall conduct a study, and submit a report to Congress by not later than June 1, 2004, on the need for current data, and sources of current data available, to determine the solvency and financial circumstances of hospitals and other medicare providers of services. The Commission shall examine data on uncompensated care, as well as the share of uncompensated care accounted for by the expenses for treating illegal aliens.

(2) USE OF TAX-RELATED RETURNS.—Using return information provided under Form 990 of the Internal Rev-

1 enue Service, the Commission shall submit to Congress, by
2 not later than June 1, 2004, a report on the following:

3 (A) Investments, endowments, and fundraising of
4 hospitals participating under the medicare program and
5 related foundations.

6 (B) Access to capital financing for private and for
7 not-for-profit hospitals.

8 **SEC. 732. DEMONSTRATION PROJECT FOR MEDICAL**
9 **ADULT DAY CARE SERVICES.**

10 (a) ESTABLISHMENT.—Subject to the succeeding provi-
11 sions of this section, the Secretary of Health and Human Serv-
12 ices shall establish a demonstration project (in this section re-
13 ferred to as the “demonstration project”) under which the Sec-
14 retary shall, as part of a plan of an episode of care for home
15 health services established for a medicare beneficiary, permit a
16 home health agency, directly or under arrangements with a
17 medical adult day care facility, to provide medical adult day
18 care services as a substitute for a portion of home health serv-
19 ices that would otherwise be provided in the beneficiary’s home.

20 (b) PAYMENT.—

21 (1) IN GENERAL.—The amount of payment for an epi-
22 sode of care for home health services, a portion of which
23 consists of substitute medical adult day care services, under
24 the demonstration project shall be made at a rate equal to
25 95 percent of the amount that would otherwise apply for
26 such home health services under section 1895 of the Social
27 Security Act (42 u.s.c. 1395fff). In no case may a home
28 health agency, or a medical adult day care facility under
29 arrangements with a home health agency, separately charge
30 a beneficiary for medical adult day care services furnished
31 under the plan of care.

32 (2) BUDGET NEUTRALITY FOR DEMONSTRATION
33 PROJECT.—Notwithstanding any other provision of law, the
34 Secretary shall provide for an appropriate reduction in the
35 aggregate amount of additional payments made under sec-
36 tion 1895 of the Social Security Act (42 U.S.C. 1395fff)
37 to reflect any increase in amounts expended from the Trust

1 Funds as a result of the demonstration project conducted
2 under this section.

3 (c) DEMONSTRATION PROJECT SITES.—The project estab-
4 lished under this section shall be conducted in not more than
5 5 States selected by the Secretary that license or certify pro-
6 viders of services that furnish medical adult day care services.

7 (d) DURATION.—The Secretary shall conduct the dem-
8 onstration project for a period of 3 years.

9 (e) VOLUNTARY PARTICIPATION.—Participation of medi-
10 care beneficiaries in the demonstration project shall be vol-
11 untary. The total number of such beneficiaries that may par-
12 ticipate in the project at any given time may not exceed
13 15,000.

14 (f) PREFERENCE IN SELECTING AGENCIES.—In selecting
15 home health agencies to participate under the demonstration
16 project, the Secretary shall give preference to those agencies
17 that are currently licensed or certified through common owner-
18 ship and control to furnish medical adult day care services.

19 (g) WAIVER AUTHORITY.—The Secretary may waive such
20 requirements of title XVIII of the Social Security Act as may
21 be necessary for the purposes of carrying out the demonstra-
22 tion project, other than waiving the requirement that an indi-
23 vidual be homebound in order to be eligible for benefits for
24 home health services.

25 (h) EVALUATION AND REPORT.—The Secretary shall con-
26 duct an evaluation of the clinical and cost effectiveness of the
27 demonstration project. Not later 30 months after the com-
28 mencement of the project, the Secretary shall submit to Con-
29 gress a report on the evaluation, and shall include in the report
30 the following:

31 (1) An analysis of the patient outcomes and costs of
32 furnishing care to the medicare beneficiaries participating
33 in the project as compared to such outcomes and costs to
34 beneficiaries receiving only home health services for the
35 same health conditions.

240

1 (2) Such recommendations regarding the extension,
2 expansion, or termination of the project as the Secretary
3 determines appropriate.

4 (i) DEFINITIONS.—In this section:

5 (1) HOME HEALTH AGENCY.—The term “home health
6 agency” has the meaning given such term in section
7 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

8 (2) MEDICAL ADULT DAY CARE FACILITY.—The term
9 “medical adult day care facility” means a facility that—

10 (A) has been licensed or certified by a State to
11 furnish medical adult day care services in the State for
12 a continuous 2-year period;

13 (B) is engaged in providing skilled nursing serv-
14 ices and other therapeutic services directly or under ar-
15 rangement with a home health agency;

16 (C) meets such standards established by the Sec-
17 retary to assure quality of care and such other require-
18 ments as the Secretary finds necessary in the interest
19 of the health and safety of individuals who are fur-
20 nished services in the facility; and

21 (D) provides medical adult day care services.

22 (3) MEDICAL ADULT DAY CARE SERVICES.—The term
23 “medical adult day care services” means—

24 (A) home health service items and services de-
25 scribed in paragraphs (1) through (7) of section
26 1861(m) furnished in a medical adult day care facility;

27 (B) a program of supervised activities furnished in
28 a group setting in the facility that—

29 (i) meet such criteria as the Secretary deter-
30 mines appropriate; and

31 (ii) is designed to promote physical and mental
32 health of the individuals; and

33 (C) such other services as the Secretary may
34 specify.

35 (4) MEDICARE BENEFICIARY.—The term “medicare
36 beneficiary” means an individual entitled to benefits under

1 part A of this title, enrolled under part B of this title, or
2 both.

3 **SEC. 733. IMPROVEMENTS IN NATIONAL AND LOCAL**
4 **COVERAGE DETERMINATION PROCESS TO**
5 **RESPOND TO CHANGES IN TECHNOLOGY.**

6 (a) NATIONAL AND LOCAL COVERAGE DETERMINATION
7 PROCESS.—

8 (1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is
9 amended—

10 (A) in the third sentence of subsection (a) by in-
11 serting “consistent with subsection (k)” after “the Sec-
12 retary shall ensure”; and

13 (B) by adding at the end the following new sub-
14 section:

15 “(k) NATIONAL AND LOCAL COVERAGE DETERMINATION
16 PROCESS.—

17 “(1) CRITERIA AND EVIDENCE USED IN MAKING NA-
18 TIONAL COVERAGE DETERMINATIONS.—The Secretary shall
19 make available to the public the criteria the Secretary uses
20 in making national coverage determinations, including how
21 evidence to demonstrate that a procedure or device is rea-
22 sonable and necessary is considered.

23 “(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR
24 NATIONAL COVERAGE DETERMINATIONS.—In the case of a
25 request for a national coverage determination that—

26 “(A) does not require a technology assessment
27 from an outside entity or deliberation from the Medi-
28 care Coverage Advisory Committee, the decision on the
29 request shall be made not later than 6 months after the
30 date of the request; or

31 “(B) requires such an assessment or deliberation
32 and in which a clinical trial is not requested, the deci-
33 sion on the request shall be made not later than 12
34 months after the date of the request.

35 “(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL
36 COVERAGE DETERMINATIONS.—At the end of the 6-month

1 period that begins on the date a request for a national cov-
2 erage determination is made, the Secretary shall—

3 “(A) make a draft of proposed decision on the re-
4 quest available to the public through the Medicare
5 Internet site of the Department of Health and Human
6 Services or other appropriate means;

7 “(B) provide a 30-day period for public comment
8 on such draft;

9 “(C) make a final decision on the request within
10 60 days of the conclusion of the 30-day period referred
11 to under subparagraph (B);

12 “(D) include in such final decision summaries of
13 the public comments received and responses thereto;

14 “(E) make available to the public the clinical evi-
15 dence and other data used in making such a decision
16 when the decision differs from the recommendations of
17 the Medicare Coverage Advisory Committee; and.

18 “(F) in the case of a decision to grant the cov-
19 erage determination, assign or temporary or permanent
20 code during the 60-day period referred to in subpara-
21 graph (C).

22 “(4) CONSULTATION WITH OUTSIDE EXPERTS IN CER-
23 TAIN NATIONAL COVERAGE DETERMINATIONS.—With re-
24 spect to a request for a national coverage determination for
25 which there is not a review by the Medicare Coverage Advi-
26 sory Committee, the Secretary shall consult with appro-
27 priate outside clinical experts.

28 “(5) LOCAL COVERAGE DETERMINATION PROCESS.—
29 With respect to local coverage determinations made on or
30 after January 1, 2004—

31 “(A) PLAN TO PROMOTE CONSISTENCY OF COV-
32 ERAGE DETERMINATIONS.—The Secretary shall develop
33 a plan to evaluate new local coverage determinations to
34 determine which determinations should be adopted na-
35 tionally and to what extent greater consistency can be
36 achieved among local coverage determinations.

1 “(B) CONSULTATION.—The Secretary shall re-
2 quire the fiscal intermediaries or carriers providing
3 services within the same area to consult on all new
4 local coverage determinations within the area.

5 “(C) DISSEMINATION OF INFORMATION.—The
6 Secretary should serve as a center to disseminate infor-
7 mation on local coverage determinations among fiscal
8 intermediaries and carriers to reduce duplication of ef-
9 fort.

10 “(6) NATIONAL AND LOCAL COVERAGE DETERMINA-
11 TION DEFINED.—For purposes of this subsection, the
12 terms ‘national coverage determination’ and ‘local coverage
13 determination’ have the meaning given such terms in para-
14 graphs (1)(B) and (2)(B), respectively, of section
15 1869(f).”.

16 (2) EFFECTIVE DATE.—The amendments made by
17 paragraph (1) shall apply to national and local coverage de-
18 terminations as of January 1, 2004.

19 (b) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCI-
20 ATED WITH CERTAIN CLINICAL TRIALS.—

21 (1) IN GENERAL.—With respect to the coverage of
22 routine costs of care for beneficiaries participating in a
23 qualifying clinical trial, as set forth on the date of the en-
24 actment of this Act in National Coverage Determination
25 30-1 of the Medicare Coverage Issues Manual, the Sec-
26 retary shall deem clinical trials conducted in accordance
27 with an investigational device exemption approved under
28 section 520(g) of the Federal Food, Drug, and Cosmetic
29 Act (42 U.S.C. 360j(g)) to be automatically qualified for
30 such coverage.

31 (2) RULE OF CONSTRUCTION.—Nothing in this sub-
32 section shall be construed as authorizing or requiring the
33 Secretary to modify the regulations set forth on the date
34 of the enactment of this Act at subpart B of part 405 of
35 title 42, Code of Federal Regulations, or subpart A of part
36 411 of such title, relating to coverage of, and payment for,
37 a medical device that is the subject of an investigational de-

1 vice exemption by the Food and Drug Administration (ex-
2 cept as may be necessary to implement paragraph (1)).

3 (3) EFFECTIVE DATE.—This subsection shall apply to
4 clinical trials begun before, on, or after the date of the en-
5 actment of this Act and to items and services furnished on
6 or after such date.

7 (c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not
8 later than January 1, 2004, the Secretary shall implement re-
9 vised procedures for the issuance of temporary national
10 HCPCS codes under part B of title XVIII of the Social Secu-
11 rity Act.

12 **SEC. 734. TREATMENT OF CERTAIN PHYSICIAN PATHOL-**
13 **OGY SERVICES.**

14 (a) IN GENERAL.—Section 1848(i) (42 U.S.C. 1395w-
15 4(i)) is amended by adding at the end the following new para-
16 graph:

17 “(4) TREATMENT OF CERTAIN INPATIENT PHYSICIAN
18 PATHOLOGY SERVICES.—

19 “(A) IN GENERAL.—With respect to services fur-
20 nished on or after January 1, 2001, if an independent
21 laboratory furnishes the technical component of a phy-
22 sician pathology service to a fee-for-service medicare
23 beneficiary who is an inpatient of a covered hospital,
24 the Secretary shall treat such component as a service
25 for which payment shall be made to the laboratory
26 under this section and not as an inpatient hospital
27 service for which payment is made to the hospital
28 under section 1886(d).

29 “(B) DEFINITIONS.—In this paragraph:

30 “(i) COVERED HOSPITAL.—

31 “(I) IN GENERAL.—The term ‘covered
32 hospital’ means, with respect to an inpatient or
33 outpatient, a hospital that had an arrangement
34 with an independent laboratory that was in ef-
35 fect as of July 22, 1999, under which a labora-
36 tory furnished the technical component of phy-
37 sician pathology services to fee-for-service

1 medicare beneficiaries who were hospital inpa-
2 tients or outpatients, respectively, and sub-
3 mitted claims for payment for such component
4 to a carrier with a contract under section 1842
5 and not to the hospital.

6 “(II) CHANGE IN OWNERSHIP DOES NOT
7 AFFECT DETERMINATION.—A change in owner-
8 ship with respect to a hospital on or after the
9 date referred to in subclause (I) shall not affect
10 the determination of whether such hospital is a
11 covered hospital for purposes of such subclause.

12 “(ii) FEE-FOR-SERVICE MEDICARE BENE-
13 FICIARY.—The term ‘fee-for-service medicare bene-
14 ficiary’ means an individual who is entitled to bene-
15 fits under part A, or enrolled under this part, or
16 both, but is not enrolled in any of the following:

17 “(I) A Medicare+ Choice plan under part
18 C.

19 “(II) A plan offered by an eligible organi-
20 zation under section 1876.

21 “(III) A program of all-inclusive care for
22 the elderly (PACE) under section 1894.

23 “(IV) A social health maintenance organi-
24 zation (SHMO) demonstration project estab-
25 lished under section 4018(b) of the Omnibus
26 Budget Reconciliation Act of 1987 (Public Law
27 100–203).”.

28 (b) CONFORMING AMENDMENT.—Section 542 of the Medi-
29 care, Medicaid, and SCHIP Benefits Improvement and Protec-
30 tion Act of 2000 (114 Stat. 2763A–550), as enacted into law
31 by section 1(a)(6) of Public Law 106–554, is repealed.

32 (c) EFFECTIVE DATES.—The amendments made by this
33 section shall take effect as if included in the enactment of the
34 Medicare, Medicaid, and SCHIP Benefits Improvement and
35 Protection Act of 2000 (Appendix F, 114 Stat. 2763A–463),
36 as enacted into law by section 1(a)(6) of Public Law 106–554.

**TITLE VIII—MEDICARE BENEFITS
ADMINISTRATION**

SEC. 801. ESTABLISHMENT OF MEDICARE BENEFITS ADMINISTRATION.

(a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et seq.), as amended by sections 105 and 721, is amended by inserting after 1808 the following new section:

“MEDICARE BENEFITS ADMINISTRATION

“SEC. 1809. (a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an agency to be known as the Medicare Benefits Administration.

“(b) ADMINISTRATOR; DEPUTY ADMINISTRATOR; CHIEF ACTUARY.—

“(1) ADMINISTRATOR.—

“(A) IN GENERAL.—The Medicare Benefits Administration shall be headed by an administrator to be known as the ‘Medicare Benefits Administrator’ (in this section referred to as the ‘Administrator’) who shall be appointed by the President, by and with the advice and consent of the Senate. The Administrator shall be in direct line of authority to the Secretary.

“(B) COMPENSATION.—The Administrator shall be paid at the rate of basic pay payable for level III of the Executive Schedule under section 5314 of title 5, United States Code.

“(C) TERM OF OFFICE.—The Administrator shall be appointed for a term of 4 years. In any case in which a successor does not take office at the end of an Administrator’s term of office, that Administrator may continue in office until the entry upon office of such a successor. An Administrator appointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

“(D) GENERAL AUTHORITY.—The Administrator shall be responsible for the exercise of all powers and the discharge of all duties of the Administration, and

1 shall have authority and control over all personnel and
2 activities thereof.

3 “(E) RULEMAKING AUTHORITY.—The Adminis-
4 trator may prescribe such rules and regulations as the
5 Administrator determines necessary or appropriate to
6 carry out the functions of the Administration. The reg-
7 ulations prescribed by the Administrator shall be sub-
8 ject to the rulemaking procedures established under
9 section 553 of title 5, United States Code. The Admin-
10 istrator shall provide for the issuance of new regula-
11 tions to carry out parts C, D, and E.

12 “(F) AUTHORITY TO ESTABLISH ORGANIZATIONAL
13 UNITS.—The Administrator may establish, alter, con-
14 solidate, or discontinue such organizational units or
15 components within the Administration as the Adminis-
16 trator considers necessary or appropriate, except as
17 specified in this section.

18 “(G) AUTHORITY TO DELEGATE.—The Adminis-
19 trator may assign duties, and delegate, or authorize
20 successive redelegations of, authority to act and to
21 render decisions, to such officers and employees of the
22 Administration as the Administrator may find nec-
23 essary. Within the limitations of such delegations, re-
24 delegations, or assignments, all official acts and deci-
25 sions of such officers and employees shall have the
26 same force and effect as though performed or rendered
27 by the Administrator.

28 “(2) DEPUTY ADMINISTRATOR.—

29 “(A) IN GENERAL.—There shall be a Deputy Ad-
30 ministrator of the Medicare Benefits Administration
31 who shall be appointed by the President, by and with
32 the advice and consent of the Senate.

33 “(B) COMPENSATION.—The Deputy Administrator
34 shall be paid at the rate of basic pay payable for level
35 IV of the Executive Schedule under section 5315 of
36 title 5, United States Code.

1 “(C) TERM OF OFFICE.—The Deputy Adminis-
2 trator shall be appointed for a term of 4 years. In any
3 case in which a successor does not take office at the
4 end of a Deputy Administrator’s term of office, such
5 Deputy Administrator may continue in office until the
6 entry upon office of such a successor. A Deputy Ad-
7 ministrator appointed to a term of office after the com-
8 mencement of such term may serve under such ap-
9 pointment only for the remainder of such term.

10 “(D) DUTIES.—The Deputy Administrator shall
11 perform such duties and exercise such powers as the
12 Administrator shall from time to time assign or dele-
13 gate. The Deputy Administrator shall be Acting Ad-
14 ministrator of the Administration during the absence or
15 disability of the Administrator and, unless the Presi-
16 dent designates another officer of the Government as
17 Acting Administrator, in the event of a vacancy in the
18 office of the Administrator.

19 “(3) CHIEF ACTUARY.—

20 “(A) IN GENERAL.—There is established in the
21 Administration the position of Chief Actuary. The
22 Chief Actuary shall be appointed by, and in direct line
23 of authority to, the Administrator of such Administra-
24 tion. The Chief Actuary shall be appointed from among
25 individuals who have demonstrated, by their education
26 and experience, superior expertise in the actuarial
27 sciences. The Chief Actuary may be removed only for
28 cause.

29 “(B) COMPENSATION.—The Chief Actuary shall
30 be compensated at the highest rate of basic pay for the
31 Senior Executive Service under section 5382(b) of title
32 5, United States Code.

33 “(C) DUTIES.—The Chief Actuary shall exercise
34 such duties as are appropriate for the office of the
35 Chief Actuary and in accordance with professional
36 standards of actuarial independence.

1 “(4) SECRETARIAL COORDINATION OF PROGRAM AD-
2 MINISTRATION.—The Secretary shall ensure appropriate
3 coordination between the Administrator and the Adminis-
4 trator of the Centers for Medicare & Medicaid Services in
5 carrying out the programs under this title.

6 “(c) DUTIES; ADMINISTRATIVE PROVISIONS.—

7 “(1) DUTIES.—

8 “(A) GENERAL DUTIES.—The Administrator shall
9 carry out parts C, D, and E, including—

10 “(i) negotiating, entering into, and enforcing,
11 contracts with plans for the offering of Medicare
12 Advantage plans under part C and EFFS plans
13 under part E, including the offering of qualified
14 prescription drug coverage under such plans; and

15 “(ii) negotiating, entering into, and enforcing,
16 contracts with PDP sponsors for the offering of
17 prescription drug plans under part D.

18 “(B) OTHER DUTIES.—The Administrator shall
19 carry out any duty provided for under part C, part D,
20 or part E, including demonstration projects carried out
21 in part or in whole under such parts, the programs of
22 all-inclusive care for the elderly (PACE program) under
23 section 1894, the social health maintenance organiza-
24 tion (SHMO) demonstration projects (referred to in
25 section 4104(c) of the Balanced Budget Act of 1997),
26 medicare cost contractors under section 1876(h), and
27 through a Medicare Advantage project that dem-
28 onstrates the application of capitation payment rates
29 for frail elderly medicare beneficiaries through the use
30 of a interdisciplinary team and through the provision of
31 primary care services to such beneficiaries by means of
32 such a team at the nursing facility involved).

33 “(C) PRESCRIPTION DRUG CARD.—The Adminis-
34 trator shall carry out section 1807 (relating to the
35 medicare prescription drug discount card endorsement
36 program).

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1 “(D) NONINTERFERENCE.—In carrying out its
2 duties with respect to the provision of qualified pre-
3 scription drug coverage to beneficiaries under this title,
4 the Administrator may not—

5 “(i) require a particular formulary or institute
6 a price structure for the reimbursement of covered
7 outpatient drugs;

8 “(ii) interfere in any way with negotiations be-
9 tween PDP sponsors and Medicare Advantage or-
10 ganizations and EFFS organizations and drug
11 manufacturers, wholesalers, or other suppliers of
12 covered outpatient drugs; and

13 “(iii) otherwise interfere with the competitive
14 nature of providing such coverage through such
15 sponsors and organizations.

16 “(E) ANNUAL REPORTS.—Not later March 31 of
17 each year, the Administrator shall submit to Congress
18 and the President a report on the administration of
19 parts C, D, and E during the previous fiscal year.

20 “(2) STAFF.—

21 “(A) IN GENERAL.—The Administrator, with the
22 approval of the Secretary, may employ, without regard
23 to chapter 31 of title 5, United States Code, other than
24 sections 3102 through 3113, 3131, 3133, 3136, 3151,
25 and 3161, such officers and employees as are necessary
26 to administer the activities to be carried out through
27 the Medicare Benefits Administration. The Adminis-
28 trator shall employ staff with appropriate and nec-
29 essary expertise in negotiating contracts in the private
30 sector.

31 “(B) FLEXIBILITY WITH RESPECT TO COMPENSA-
32 TION.—

33 “(i) IN GENERAL.—The staff of the Medicare
34 Benefits Administration shall, subject to clause (ii),
35 be paid without regard to the provisions of chapter
36 51 (other than section 5101) and chapter 53 (other
37 than section 5301, sections 5303 through 5305,

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1 5311, and 5372 of such title (relating to classifica-
2 tion and schedule pay rates).

3 “(ii) MAXIMUM RATE.—In no case may the
4 rate of compensation determined under clause (i)
5 exceed the rate of basic pay payable for level IV of
6 the Executive Schedule under section 5315 of title
7 5, United States Code.

8 “(C) LIMITATION ON FULL-TIME EQUIVALENT
9 STAFFING FOR CURRENT CMS FUNCTIONS BEING
10 TRANSFERRED.—The Administrator may not employ
11 under this paragraph a number of full-time equivalent
12 employees, to carry out functions that were previously
13 conducted by the Centers for Medicare & Medicaid
14 Services and that are conducted by the Administrator
15 by reason of this section, that exceeds the number of
16 such full-time equivalent employees authorized to be
17 employed by the Centers for Medicare & Medicaid Serv-
18 ices to conduct such functions as of the date of the en-
19 actment of this Act.

20 “(3) REDELEGATION OF CERTAIN FUNCTIONS OF THE
21 CENTERS FOR MEDICARE & MEDICAID SERVICES.—

22 “(A) IN GENERAL.—The Secretary, the Adminis-
23 trator, and the Administrator of the Centers for Medi-
24 care & Medicaid Services shall establish an appropriate
25 transition of responsibility in order to redelegate the
26 administration of part C from the Secretary and the
27 Administrator of the Centers for Medicare & Medicaid
28 Services to the Administrator as is appropriate to carry
29 out the purposes of this section.

30 “(B) TRANSFER OF DATA AND INFORMATION.—
31 The Secretary shall ensure that the Administrator of
32 the Centers for Medicare & Medicaid Services transfers
33 to the Administrator of the Medicare Benefits Adminis-
34 tration such information and data in the possession of
35 the Administrator of the Centers for Medicare & Med-
36 icaid Services as the Administrator of the Medicare

1 Benefits Administration requires to carry out the du-
2 ties described in paragraph (1).

3 “(C) CONSTRUCTION.—Insofar as a responsibility
4 of the Secretary or the Administrator of the Centers
5 for Medicare & Medicaid Services is redelegated to the
6 Administrator under this section, any reference to the
7 Secretary or the Administrator of the Centers for Medi-
8 care & Medicaid Services in this title or title XI with
9 respect to such responsibility is deemed to be a ref-
10 erence to the Administrator.

11 “(d) OFFICE OF BENEFICIARY ASSISTANCE.—

12 “(1) ESTABLISHMENT.—The Secretary shall establish
13 within the Medicare Benefits Administration an Office of
14 Beneficiary Assistance to coordinate functions relating to
15 outreach and education of medicare beneficiaries under this
16 title, including the functions described in paragraph (2).
17 The Office shall be separate operating division within the
18 Administration.

19 “(2) DISSEMINATION OF INFORMATION ON BENEFITS
20 AND APPEALS RIGHTS.—

21 “(A) DISSEMINATION OF BENEFITS INFORMA-
22 TION.—The Office of Beneficiary Assistance shall dis-
23 seminate, directly or through contract, to medicare
24 beneficiaries, by mail, by posting on the Internet site
25 of the Medicare Benefits Administration and through a
26 toll-free telephone number, information with respect to
27 the following:

28 “(i) Benefits, and limitations on payment (in-
29 cluding cost-sharing, stop-loss provisions, and for-
30 mulary restrictions) under parts C, D, and E.

31 “(ii) Benefits, and limitations on payment
32 under parts A and B, including information on
33 medicare supplemental policies under section 1882.
34 Such information shall be presented in a manner so
35 that medicare beneficiaries may compare benefits under
36 parts A, B, D, and medicare supplemental policies with

1 benefits under Medicare Advantage plans under part C
2 and EFFS plans under part E.

3 “(B) DISSEMINATION OF APPEALS RIGHTS INFOR-
4 MATION.—The Office of Beneficiary Assistance shall
5 disseminate to medicare beneficiaries in the manner
6 provided under subparagraph (A) a description of pro-
7 cedural rights (including grievance and appeals proce-
8 dures) of beneficiaries under the original medicare fee-
9 for-service program under parts A and B, the Medicare
10 Advantage program under part C, the Voluntary Pre-
11 scription Drug Benefit Program under part D, and the
12 Enhanced Fee-for-Service program under part E.

13 “(e) MEDICARE POLICY ADVISORY BOARD.—

14 “(1) ESTABLISHMENT.—There is established within
15 the Medicare Benefits Administration the Medicare Policy
16 Advisory Board (in this section referred to the ‘Board’).
17 The Board shall advise, consult with, and make rec-
18 ommendations to the Administrator of the Medicare Bene-
19 fits Administration with respect to the administration of
20 parts C, D, and E, including the review of payment policies
21 under such parts.

22 “(2) REPORTS.—

23 “(A) IN GENERAL.—With respect to matters of
24 the administration of parts C, D, and E the Board
25 shall submit to Congress and to the Administrator of
26 the Medicare Benefits Administration such reports as
27 the Board determines appropriate. Each such report
28 may contain such recommendations as the Board deter-
29 mines appropriate for legislative or administrative
30 changes to improve the administration of such parts,
31 including the topics described in subparagraph (B).
32 Each such report shall be published in the Federal
33 Register.

34 “(B) TOPICS DESCRIBED.—Reports required
35 under subparagraph (A) may include the following top-
36 ics:

1 “(i) FOSTERING COMPETITION.—Rec-
2 ommendations or proposals to increase competition
3 under parts C, D, and E for services furnished to
4 medicare beneficiaries.

5 “(ii) EDUCATION AND ENROLLMENT.—Rec-
6 ommendations for the improvement to efforts to
7 provide medicare beneficiaries information and edu-
8 cation on the program under this title, and specifi-
9 cally parts C, D, and E, and the program for en-
10 rollment under the title.

11 “(iii) IMPLEMENTATION OF RISK-ADJUST-
12 MENT.—Evaluation of the implementation under
13 section 1853(a)(3)(C) of the risk adjustment meth-
14 odology to payment rates under that section to
15 Medicare Advantage organizations offering Medi-
16 care Advantage plans (and the corresponding pay-
17 ment provisions under part E) that accounts for
18 variations in per capita costs based on health sta-
19 tus, geography, and other demographic factors.

20 “(iv) RURAL ACCESS.—Recommendations to
21 improve competition and access to plans under
22 parts C, D, and E in rural areas.

23 “(C) MAINTAINING INDEPENDENCE OF BOARD.—
24 The Board shall directly submit to Congress reports re-
25 quired under subparagraph (A). No officer or agency of
26 the United States may require the Board to submit to
27 any officer or agency of the United States for approval,
28 comments, or review, prior to the submission to Con-
29 gress of such reports.

30 “(3) DUTY OF ADMINISTRATOR OF MEDICARE BENE-
31 FITS ADMINISTRATION.—With respect to any report sub-
32 mitted by the Board under paragraph (2)(A), not later
33 than 90 days after the report is submitted, the Adminis-
34 trator of the Medicare Benefits Administration shall submit
35 to Congress and the President an analysis of recommenda-
36 tions made by the Board in such report. Each such analysis
37 shall be published in the Federal Register.

1 “(4) MEMBERSHIP.—

2 “(A) APPOINTMENT.—Subject to the succeeding
3 provisions of this paragraph, the Board shall consist of
4 seven members to be appointed as follows:

5 “(i) Three members shall be appointed by the
6 President.

7 “(ii) Two members shall be appointed by the
8 Speaker of the House of Representatives, with the
9 advice of the chairmen and the ranking minority
10 members of the Committees on Ways and Means
11 and on Energy and Commerce of the House of
12 Representatives.

13 “(iii) Two members shall be appointed by the
14 President pro tempore of the Senate with the ad-
15 vice of the chairman and the ranking minority
16 member of the Senate Committee on Finance.

17 “(B) QUALIFICATIONS.—The members shall be
18 chosen on the basis of their integrity, impartiality, and
19 good judgment, and shall be individuals who are, by
20 reason of their education and experience in health care
21 benefits management, exceptionally qualified to perform
22 the duties of members of the Board.

23 “(C) PROHIBITION ON INCLUSION OF FEDERAL
24 EMPLOYEES.—No officer or employee of the United
25 States may serve as a member of the Board.

26 “(5) COMPENSATION.—Members of the Board shall
27 receive, for each day (including travel time) they are en-
28 gaged in the performance of the functions of the board,
29 compensation at rates not to exceed the daily equivalent to
30 the annual rate in effect for level IV of the Executive
31 Schedule under section 5315 of title 5, United States Code.

32 “(6) TERMS OF OFFICE.—

33 “(A) IN GENERAL.—The term of office of mem-
34 bers of the Board shall be 3 years.

35 “(B) TERMS OF INITIAL APPOINTEES.—As des-
36 ignated by the President at the time of appointment,
37 of the members first appointed—

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1 “(i) one shall be appointed for a term of 1
2 year;

3 “(ii) three shall be appointed for terms of 2
4 years; and

5 “(iii) three shall be appointed for terms of 3
6 years.

7 “(C) REAPPOINTMENTS.—Any person appointed
8 as a member of the Board may not serve for more than
9 8 years.

10 “(D) VACANCY.—Any member appointed to fill a
11 vacancy occurring before the expiration of the term for
12 which the member’s predecessor was appointed shall be
13 appointed only for the remainder of that term. A mem-
14 ber may serve after the expiration of that member’s
15 term until a successor has taken office. A vacancy in
16 the Board shall be filled in the manner in which the
17 original appointment was made.

18 “(7) CHAIR.—The Chair of the Board shall be elected
19 by the members. The term of office of the Chair shall be
20 3 years.

21 “(8) MEETINGS.—The Board shall meet at the call of
22 the Chair, but in no event less than three times during
23 each fiscal year.

24 “(9) DIRECTOR AND STAFF.—

25 “(A) APPOINTMENT OF DIRECTOR.—The Board
26 shall have a Director who shall be appointed by the
27 Chair.

28 “(B) IN GENERAL.—With the approval of the
29 Board, the Director may appoint, without regard to
30 chapter 31 of title 5, United States Code, such addi-
31 tional personnel as the Director considers appropriate.

32 “(C) FLEXIBILITY WITH RESPECT TO COMPENSA-
33 TION.—

34 “(i) IN GENERAL.—The Director and staff of
35 the Board shall, subject to clause (ii), be paid with-
36 out regard to the provisions of chapter 51 and

chapter 53 of such title (relating to classification and schedule pay rates).

“(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

“(D) ASSISTANCE FROM THE ADMINISTRATOR OF THE MEDICARE BENEFITS ADMINISTRATION.—The Administrator of the Medicare Benefits Administration shall make available to the Board such information and other assistance as it may require to carry out its functions.

“(10) CONTRACT AUTHORITY.—The Board may contract with and compensate government and private agencies or persons to carry out its duties under this subsection, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

“(f) FUNDING.—There is authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Medicare Prescription Drug Account), such sums as are necessary to carry out this section.”.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

(2) DUTIES WITH RESPECT TO ELIGIBILITY DETERMINATIONS AND ENROLLMENT.—The Administrator of the Medicare Benefits Administration shall carry out enrollment under title XVIII of the Social Security Act, make eligibility determinations under such title, and carry out parts C and E of such title for years beginning or after January 1, 2006.

(3) TRANSITION.—Before the date the Administrator of the Medicare Benefits Administration is appointed and assumes responsibilities under this section and section

1 1807 of the Social Security Act, the Secretary of Health
2 and Human Services shall provide for the conduct of any
3 responsibilities of such Administrator that are otherwise
4 provided under law.

5 (c) MISCELLANEOUS ADMINISTRATIVE PROVISIONS.—

6 (1) ADMINISTRATOR AS MEMBER OF THE BOARD OF
7 TRUSTEES OF THE MEDICARE TRUST FUNDS.—Section
8 1817(b) and section 1841(b) (42 U.S.C. 1395i(b),
9 1395t(b)) are each amended by striking “and the Secretary
10 of Health and Human Services, all ex officio,” and insert-
11 ing “the Secretary of Health and Human Services, and the
12 Administrator of the Medicare Benefits Administration, all
13 ex officio,”.

14 (2) INCREASE IN GRADE TO EXECUTIVE LEVEL III FOR
15 THE ADMINISTRATOR OF THE CENTERS FOR MEDICARE &
16 MEDICAID SERVICES; LEVEL FOR MEDICARE BENEFITS AD-
17 MINISTRATOR.—

18 (A) IN GENERAL.—Section 5314 of title 5, United
19 States Code, by adding at the end the following:

20 “Administrator of the Centers for Medicare & Med-
21 icaid Services.

22 “Administrator of the Medicare Benefits Administra-
23 tion.”.

24 (B) CONFORMING AMENDMENT.—Section 5315 of
25 such title is amended by striking “Administrator of the
26 Health Care Financing Administration.”.

27 (C) EFFECTIVE DATE.—The amendments made by
28 this paragraph take effect on January 1, 2004.

29 **TITLE IX—REGULATORY REDUC-**
30 **TION AND CONTRACTING RE-**
31 **FORM**

32 **Subtitle A—Regulatory Reform**

33 **SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.**

34 (a) CONSTRUCTION.—Nothing in this title shall be
35 construed—

(1) to compromise or affect existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement, or administrative remedies, including under sections 3729 through 3733 of title 31, United States Code (known as the False Claims Act); or

(2) to prevent or impede the Department of Health and Human Services in any way from its ongoing efforts to eliminate waste, fraud, and abuse in the medicare program.

Furthermore, the consolidation of medicare administrative contracting set forth in this Act does not constitute consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund or reflect any position on that issue.

(b) DEFINITION OF SUPPLIER.—Section 1861 (42 U.S.C. 1395x) is amended by inserting after subsection (c) the following new subsection:

“Supplier

“(d) The term ‘supplier’ means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.”.

SEC. 902. ISSUANCE OF REGULATIONS.

(a) REGULAR TIMELINE FOR PUBLICATION OF FINAL RULES.—

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)) is amended by adding at the end the following new paragraph:

“(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

“(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under ex-

1 ceptional circumstances. If the Secretary intends to vary such
2 timeline with respect to the publication of a final regulation,
3 the Secretary shall cause to have published in the Federal Reg-
4 ister notice of the different timeline by not later than the
5 timeline previously established with respect to such regulation.
6 Such notice shall include a brief explanation of the justification
7 for such variation.

8 “(C) In the case of interim final regulations, upon the ex-
9 piration of the regular timeline established under this para-
10 graph for the publication of a final regulation after opportunity
11 for public comment, the interim final regulation shall not con-
12 tinue in effect unless the Secretary publishes (at the end of the
13 regular timeline and, if applicable, at the end of each suc-
14 ceeding 1-year period) a notice of continuation of the regulation
15 that includes an explanation of why the regular timeline (and
16 any subsequent 1-year extension) was not complied with. If
17 such a notice is published, the regular timeline (or such
18 timeline as previously extended under this paragraph) for publi-
19 cation of the final regulation shall be treated as having been
20 extended for 1 additional year.

21 “(D) The Secretary shall annually submit to Congress a
22 report that describes the instances in which the Secretary failed
23 to publish a final regulation within the applicable regular
24 timeline under this paragraph and that provides an explanation
25 for such failures.”.

26 (2) EFFECTIVE DATE.—The amendment made by
27 paragraph (1) shall take effect on the date of the enact-
28 ment of this Act. The Secretary shall provide for an appro-
29 priate transition to take into account the backlog of pre-
30 viously published interim final regulations.

31 (b) LIMITATIONS ON NEW MATTER IN FINAL REGULA-
32 TIONS.—

33 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
34 1395hh(a)), as amended by subsection (a), is amended by
35 adding at the end the following new paragraph:

36 “(4) If the Secretary publishes a final regulation that in-
37 cludes a provision that is not a logical outgrowth of a pre-

1 viously published notice of proposed rulemaking or interim final
2 rule, such provision shall be treated as a proposed regulation
3 and shall not take effect until there is the further opportunity
4 for public comment and a publication of the provision again as
5 a final regulation.”.

6 (2) EFFECTIVE DATE.—The amendment made by
7 paragraph (1) shall apply to final regulations published on
8 or after the date of the enactment of this Act.

9 **SEC. 903. COMPLIANCE WITH CHANGES IN REGULA-**
10 **TIONS AND POLICIES.**

11 (a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE
12 CHANGES.—

13 (1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh),
14 as amended by section 902(a), is amended by adding at the
15 end the following new subsection:

16 “(e)(1)(A) A substantive change in regulations, manual in-
17 structions, interpretative rules, statements of policy, or guide-
18 lines of general applicability under this title shall not be applied
19 (by extrapolation or otherwise) retroactively to items and serv-
20 ices furnished before the effective date of the change, unless
21 the Secretary determines that—

22 “(i) such retroactive application is necessary to comply
23 with statutory requirements; or

24 “(ii) failure to apply the change retroactively would be
25 contrary to the public interest.”.

26 (2) EFFECTIVE DATE.—The amendment made by
27 paragraph (1) shall apply to substantive changes issued on
28 or after the date of the enactment of this Act.

29 (b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE
30 CHANGES AFTER NOTICE.—

31 (1) IN GENERAL.—Section 1871(e)(1), as added by
32 subsection (a), is amended by adding at the end the fol-
33 lowing:

34 “(B)(i) Except as provided in clause (ii), a substantive
35 change referred to in subparagraph (A) shall not become effec-
36 tive before the end of the 30-day period that begins on the date

1 that the Secretary has issued or published, as the case may be,
2 the substantive change.

3 “(ii) The Secretary may provide for such a substantive
4 change to take effect on a date that precedes the end of the
5 30-day period under clause (i) if the Secretary finds that waiv-
6 er of such 30-day period is necessary to comply with statutory
7 requirements or that the application of such 30-day period is
8 contrary to the public interest. If the Secretary provides for an
9 earlier effective date pursuant to this clause, the Secretary
10 shall include in the issuance or publication of the substantive
11 change a finding described in the first sentence, and a brief
12 statement of the reasons for such finding.

13 “(C) No action shall be taken against a provider of serv-
14 ices or supplier with respect to noncompliance with such a sub-
15 stantive change for items and services furnished before the ef-
16 fective date of such a change.”.

17 (2) EFFECTIVE DATE.—The amendment made by
18 paragraph (1) shall apply to compliance actions undertaken
19 on or after the date of the enactment of this Act.

20 (c) RELIANCE ON GUIDANCE.—

21 (1) IN GENERAL.—Section 1871(e), as added by sub-
22 section (a), is further amended by adding at the end the
23 following new paragraph:

24 “(2)(A) If—

25 “(i) a provider of services or supplier follows the writ-
26 ten guidance (which may be transmitted electronically) pro-
27 vided by the Secretary or by a medicare contractor (as de-
28 fined in section 1889(g)) acting within the scope of the
29 contractor’s contract authority, with respect to the fur-
30 nishing of items or services and submission of a claim for
31 benefits for such items or services with respect to such pro-
32 vider or supplier;

33 “(ii) the Secretary determines that the provider of
34 services or supplier has accurately presented the cir-
35 cumstances relating to such items, services, and claim to
36 the contractor in writing; and

37 “(iii) the guidance was in error;

1 the provider of services or supplier shall not be subject to any
2 sanction (including any penalty or requirement for repayment
3 of any amount) if the provider of services or supplier reason-
4 ably relied on such guidance.

5 “(B) Subparagraph (A) shall not be construed as pre-
6 venting the recoupment or repayment (without any additional
7 penalty) relating to an overpayment insofar as the overpayment
8 was solely the result of a clerical or technical operational
9 error.”.

10 (2) EFFECTIVE DATE.—The amendment made by
11 paragraph (1) shall take effect on the date of the enact-
12 ment of this Act but shall not apply to any sanction for
13 which notice was provided on or before the date of the en-
14 actment of this Act.

15 **SEC. 904. REPORTS AND STUDIES RELATING TO REGU-**
16 **LATORY REFORM.**

17 (a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

18 (1) STUDY.—The Comptroller General of the United
19 States shall conduct a study to determine the feasibility
20 and appropriateness of establishing in the Secretary au-
21 thority to provide legally binding advisory opinions on ap-
22 propriate interpretation and application of regulations to
23 carry out the medicare program under title XVIII of the
24 Social Security Act. Such study shall examine the appro-
25 priate timeframe for issuing such advisory opinions, as well
26 as the need for additional staff and funding to provide such
27 opinions.

28 (2) REPORT.—The Comptroller General shall submit
29 to Congress a report on the study conducted under para-
30 graph (1) by not later than one year after the date of the
31 enactment of this Act.

32 (b) REPORT ON LEGAL AND REGULATORY INCONSIST-
33 ENCIES.—Section 1871 (42 U.S.C. 1395hh), as amended by
34 section 2(a), is amended by adding at the end the following new
35 subsection:

36 “(f)(1) Not later than 2 years after the date of the enact-
37 ment of this subsection, and every 2 years thereafter, the Sec-

1 retary shall submit to Congress a report with respect to the ad-
2 ministration of this title and areas of inconsistency or conflict
3 among the various provisions under law and regulation.

4 “(2) In preparing a report under paragraph (1), the Sec-
5 retary shall collect—

6 “(A) information from individuals entitled to benefits
7 under part A or enrolled under part B, or both, providers
8 of services, and suppliers and from the Medicare Bene-
9 ficiary Ombudsman and the Medicare Provider Ombuds-
10 man with respect to such areas of inconsistency and con-
11 flict; and

12 “(B) information from medicare contractors that
13 tracks the nature of written and telephone inquiries.

14 “(3) A report under paragraph (1) shall include a descrip-
15 tion of efforts by the Secretary to reduce such inconsistency or
16 conflicts, and recommendations for legislation or administrative
17 action that the Secretary determines appropriate to further re-
18 duce such inconsistency or conflicts.”.

19 **Subtitle B—Contracting Reform**

20 **SEC. 911. INCREASED FLEXIBILITY IN MEDICARE AD-** 21 **MINISTRATION.**

22 (a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE AD-
23 MINISTRATION.—

24 (1) IN GENERAL.—Title XVIII is amended by insert-
25 ing after section 1874 the following new section:

26 “CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

27 “SEC. 1874A. (a) AUTHORITY.—

28 “(1) AUTHORITY TO ENTER INTO CONTRACTS.—The
29 Secretary may enter into contracts with any eligible entity
30 to serve as a medicare administrative contractor with re-
31 spect to the performance of any or all of the functions de-
32 scribed in paragraph (4) or parts of those functions (or, to
33 the extent provided in a contract, to secure performance
34 thereof by other entities).

35 “(2) ELIGIBILITY OF ENTITIES.—An entity is eligible
36 to enter into a contract with respect to the performance of
37 a particular function described in paragraph (4) only if—

1 “(A) the entity has demonstrated capability to
2 carry out such function;

3 “(B) the entity complies with such conflict of in-
4 terest standards as are generally applicable to Federal
5 acquisition and procurement;

6 “(C) the entity has sufficient assets to financially
7 support the performance of such function; and

8 “(D) the entity meets such other requirements as
9 the Secretary may impose.

10 “(3) MEDICARE ADMINISTRATIVE CONTRACTOR DE-
11 FINED.—For purposes of this title and title XI—

12 “(A) IN GENERAL.—The term ‘medicare adminis-
13 trative contractor’ means an agency, organization, or
14 other person with a contract under this section.

15 “(B) APPROPRIATE MEDICARE ADMINISTRATIVE
16 CONTRACTOR.—With respect to the performance of a
17 particular function in relation to an individual entitled
18 to benefits under part A or enrolled under part B, or
19 both, a specific provider of services or supplier (or class
20 of such providers of services or suppliers), the ‘appro-
21 priate’ medicare administrative contractor is the medi-
22 care administrative contractor that has a contract
23 under this section with respect to the performance of
24 that function in relation to that individual, provider of
25 services or supplier or class of provider of services or
26 supplier.

27 “(4) FUNCTIONS DESCRIBED.—The functions referred
28 to in paragraphs (1) and (2) are payment functions, pro-
29 vider services functions, and functions relating to services
30 furnished to individuals entitled to benefits under part A
31 or enrolled under part B, or both, as follows:

32 “(A) DETERMINATION OF PAYMENT AMOUNTS.—
33 Determining (subject to the provisions of section 1878
34 and to such review by the Secretary as may be provided
35 for by the contracts) the amount of the payments re-
36 quired pursuant to this title to be made to providers of
37 services, suppliers and individuals.

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1 “(B) MAKING PAYMENTS.—Making payments de-
2 scribed in subparagraph (A) (including receipt, dis-
3 bursement, and accounting for funds in making such
4 payments).

5 “(C) BENEFICIARY EDUCATION AND ASSIST-
6 ANCE.—Providing education and outreach to individ-
7 uals entitled to benefits under part A or enrolled under
8 part B, or both, and providing assistance to those indi-
9 viduals with specific issues, concerns or problems.

10 “(D) PROVIDER CONSULTATIVE SERVICES.—Pro-
11 viding consultative services to institutions, agencies,
12 and other persons to enable them to establish and
13 maintain fiscal records necessary for purposes of this
14 title and otherwise to qualify as providers of services or
15 suppliers.

16 “(E) COMMUNICATION WITH PROVIDERS.—Com-
17 municating to providers of services and suppliers any
18 information or instructions furnished to the medicare
19 administrative contractor by the Secretary, and facili-
20 tating communication between such providers and sup-
21 pliers and the Secretary.

22 “(F) PROVIDER EDUCATION AND TECHNICAL AS-
23 SISTANCE.—Performing the functions relating to pro-
24 vider education, training, and technical assistance.

25 “(G) ADDITIONAL FUNCTIONS.—Performing such
26 other functions as are necessary to carry out the pur-
27 poses of this title.

28 “(5) RELATIONSHIP TO MIP CONTRACTS.—

29 “(A) NONDUPLICATION OF DUTIES.—In entering
30 into contracts under this section, the Secretary shall
31 assure that functions of medicare administrative con-
32 tractors in carrying out activities under parts A and B
33 do not duplicate activities carried out under the Medi-
34 care Integrity Program under section 1893. The pre-
35 vious sentence shall not apply with respect to the activ-
36 ity described in section 1893(b)(5) (relating to prior

1 authorization of certain items of durable medical equip-
2 ment under section 1834(a)(15)).

3 “(B) CONSTRUCTION.—An entity shall not be
4 treated as a medicare administrative contractor merely
5 by reason of having entered into a contract with the
6 Secretary under section 1893.

7 “(6) APPLICATION OF FEDERAL ACQUISITION REGULA-
8 TION.—Except to the extent inconsistent with a specific re-
9 quirement of this title, the Federal Acquisition Regulation
10 applies to contracts under this title.

11 “(b) CONTRACTING REQUIREMENTS.—

12 “(1) USE OF COMPETITIVE PROCEDURES.—

13 “(A) IN GENERAL.—Except as provided in laws
14 with general applicability to Federal acquisition and
15 procurement or in subparagraph (B), the Secretary
16 shall use competitive procedures when entering into
17 contracts with medicare administrative contractors
18 under this section, taking into account performance
19 quality as well as price and other factors.

20 “(B) RENEWAL OF CONTRACTS.—The Secretary
21 may renew a contract with a medicare administrative
22 contractor under this section from term to term with-
23 out regard to section 5 of title 41, United States Code,
24 or any other provision of law requiring competition, if
25 the medicare administrative contractor has met or ex-
26 ceeded the performance requirements applicable with
27 respect to the contract and contractor, except that the
28 Secretary shall provide for the application of competi-
29 tive procedures under such a contract not less fre-
30 quently than once every five years.

31 “(C) TRANSFER OF FUNCTIONS.—The Secretary
32 may transfer functions among medicare administrative
33 contractors consistent with the provisions of this para-
34 graph. The Secretary shall ensure that performance
35 quality is considered in such transfers. The Secretary
36 shall provide public notice (whether in the Federal Reg-
37 ister or otherwise) of any such transfer (including a de-

1 scription of the functions so transferred, a description
2 of the providers of services and suppliers affected by
3 such transfer, and contact information for the contrac-
4 tors involved).

5 “(D) INCENTIVES FOR QUALITY.—The Secretary
6 shall provide incentives for medicare administrative
7 contractors to provide quality service and to promote
8 efficiency.

9 “(2) COMPLIANCE WITH REQUIREMENTS.—No con-
10 tract under this section shall be entered into with any
11 medicare administrative contractor unless the Secretary
12 finds that such medicare administrative contractor will per-
13 form its obligations under the contract efficiently and effec-
14 tively and will meet such requirements as to financial re-
15 sponsibility, legal authority, quality of services provided,
16 and other matters as the Secretary finds pertinent.

17 “(3) PERFORMANCE REQUIREMENTS.—

18 “(A) DEVELOPMENT OF SPECIFIC PERFORMANCE
19 REQUIREMENTS.—In developing contract performance
20 requirements, the Secretary shall develop performance
21 requirements applicable to functions described in sub-
22 section (a)(4).

23 “(B) CONSULTATION.— In developing such re-
24 quirements, the Secretary may consult with providers
25 of services and suppliers, organizations representing in-
26 dividuals entitled to benefits under part A or enrolled
27 under part B, or both, and organizations and agencies
28 performing functions necessary to carry out the pur-
29 poses of this section with respect to such performance
30 requirements.

31 “(C) INCLUSION IN CONTRACTS.—All contractor
32 performance requirements shall be set forth in the con-
33 tract between the Secretary and the appropriate medi-
34 care administrative contractor. Such performance
35 requirements—

1 “(i) shall reflect the performance requirements
2 developed under subparagraph (A), but may in-
3 clude additional performance requirements;

4 “(ii) shall be used for evaluating contractor
5 performance under the contract; and

6 “(iii) shall be consistent with the written state-
7 ment of work provided under the contract.

8 “(4) INFORMATION REQUIREMENTS.—The Secretary
9 shall not enter into a contract with a medicare administra-
10 tive contractor under this section unless the contractor
11 agrees—

12 “(A) to furnish to the Secretary such timely infor-
13 mation and reports as the Secretary may find nec-
14 essary in performing his functions under this title; and

15 “(B) to maintain such records and afford such ac-
16 cess thereto as the Secretary finds necessary to assure
17 the correctness and verification of the information and
18 reports under subparagraph (A) and otherwise to carry
19 out the purposes of this title.

20 “(5) SURETY BOND.—A contract with a medicare ad-
21 ministrative contractor under this section may require the
22 medicare administrative contractor, and any of its officers
23 or employees certifying payments or disbursing funds pur-
24 suant to the contract, or otherwise participating in carrying
25 out the contract, to give surety bond to the United States
26 in such amount as the Secretary may deem appropriate.

27 “(c) TERMS AND CONDITIONS.—

28 “(1) IN GENERAL.—A contract with any medicare ad-
29 ministrative contractor under this section may contain such
30 terms and conditions as the Secretary finds necessary or
31 appropriate and may provide for advances of funds to the
32 medicare administrative contractor for the making of pay-
33 ments by it under subsection (a)(4)(B).

34 “(2) PROHIBITION ON MANDATES FOR CERTAIN DATA
35 COLLECTION.—The Secretary may not require, as a condi-
36 tion of entering into, or renewing, a contract under this
37 section, that the medicare administrative contractor match

1 data obtained other than in its activities under this title
2 with data used in the administration of this title for pur-
3 poses of identifying situations in which the provisions of
4 section 1862(b) may apply.

5 “(d) LIMITATION ON LIABILITY OF MEDICARE ADMINIS-
6 TRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

7 “(1) CERTIFYING OFFICER.—No individual designated
8 pursuant to a contract under this section as a certifying of-
9 ficer shall, in the absence of the reckless disregard of the
10 individual’s obligations or the intent by that individual to
11 defraud the United States, be liable with respect to any
12 payments certified by the individual under this section.

13 “(2) DISBURSING OFFICER.—No disbursing officer
14 shall, in the absence of the reckless disregard of the offi-
15 cer’s obligations or the intent by that officer to defraud the
16 United States, be liable with respect to any payment by
17 such officer under this section if it was based upon an au-
18 thorization (which meets the applicable requirements for
19 such internal controls established by the Comptroller Gen-
20 eral) of a certifying officer designated as provided in para-
21 graph (1) of this subsection.

22 “(3) LIABILITY OF MEDICARE ADMINISTRATIVE CON-
23 TRACTOR.—

24 “(A) IN GENERAL.—No medicare administrative con-
25 tractor shall be liable to the United States for a payment
26 by a certifying or disbursing officer unless, in connection
27 with such payment, the medicare administrative contractor
28 acted with reckless disregard of its obligations under its
29 medicare administrative contract or with intent to defraud
30 the United States.

31 “(B) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing
32 in this subsection shall be construed to limit liability for
33 conduct that would constitute a violation of sections 3729
34 through 3731 of title 31, United States Code (commonly
35 known as the ‘False Claims Act’).

36 “(4) INDEMNIFICATION BY SECRETARY.—

1 “(A) IN GENERAL.—Subject to subparagraphs (B)
2 and (D), in the case of a medicare administrative con-
3 tractor (or a person who is a director, officer, or em-
4 ployee of such a contractor or who is engaged by the
5 contractor to participate directly in the claims adminis-
6 tration process) who is made a party to any judicial or
7 administrative proceeding arising from or relating di-
8 rectly to the claims administration process under this
9 title, the Secretary may, to the extent the Secretary de-
10 termines to be appropriate and as specified in the con-
11 tract with the contractor, indemnify the contractor and
12 such persons.

13 “(B) CONDITIONS.—The Secretary may not pro-
14 vide indemnification under subparagraph (A) insofar as
15 the liability for such costs arises directly from conduct
16 that is determined by the judicial proceeding or by the
17 Secretary to be criminal in nature, fraudulent, or
18 grossly negligent. If indemnification is provided by the
19 Secretary with respect to a contractor before a deter-
20 mination that such costs arose directly from such con-
21 duct, the contractor shall reimburse the Secretary for
22 costs of indemnification.

23 “(C) SCOPE OF INDEMNIFICATION.—Indemnifica-
24 tion by the Secretary under subparagraph (A) may in-
25 clude payment of judgments, settlements (subject to
26 subparagraph (D)), awards, and costs (including rea-
27 sonable legal expenses).

28 “(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A
29 contractor or other person described in subparagraph
30 (A) may not propose to negotiate a settlement or com-
31 promise of a proceeding described in such subpara-
32 graph without the prior written approval of the Sec-
33 retary to negotiate such settlement or compromise. Any
34 indemnification under subparagraph (A) with respect to
35 amounts paid under a settlement or compromise of a
36 proceeding described in such subparagraph are condi-

tioned upon prior written approval by the Secretary of the final settlement or compromise.

“(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

“(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

“(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulations.”.

(2) CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS.—In developing contract performance requirements under section 1874A(b) of the Social Security Act, as inserted by paragraph (1), the Secretary shall consider inclusion of the performance standards described in sections 1816(f)(2) of such Act (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act (relating to timely review of determinations and fair hearing requests), as such sections were in effect before the date of the enactment of this Act.

(b) CONFORMING AMENDMENTS TO SECTION 1816 (RELATING TO FISCAL INTERMEDIARIES).—Section 1816 (42 U.S.C. 1395h) is amended as follows:

(1) The heading is amended to read as follows:
“PROVISIONS RELATING TO THE ADMINISTRATION OF PART A”.

(2) Subsection (a) is amended to read as follows:

“(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.”.

(3) Subsection (b) is repealed.

(4) Subsection (c) is amended—

(A) by striking paragraph (1); and

(B) in each of paragraphs (2)(A) and (3)(A), by striking “agreement under this section” and inserting “contract under section 1874A that provides for making payments under this part”.

1 (5) Subsections (d) through (i) are repealed.

2 (6) Subsections (j) and (k) are each amended—

3 (A) by striking “An agreement with an agency or
4 organization under this section” and inserting “A con-
5 tract with a medicare administrative contractor under
6 section 1874A with respect to the administration of
7 this part”; and

8 (B) by striking “such agency or organization” and
9 inserting “such medicare administrative contractor”
10 each place it appears.

11 (7) Subsection (l) is repealed.

12 (c) CONFORMING AMENDMENTS TO SECTION 1842 (RE-
13 LATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is
14 amended as follows:

15 (1) The heading is amended to read as follows:

16 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART B”.

17 (2) Subsection (a) is amended to read as follows:

18 “(a) The administration of this part shall be conducted
19 through contracts with medicare administrative contractors
20 under section 1874A.”.

21 (3) Subsection (b) is amended—

22 (A) by striking paragraph (1);

23 (B) in paragraph (2)—

24 (i) by striking subparagraphs (A) and (B);

25 (ii) in subparagraph (C), by striking “car-
26 riers” and inserting “medicare administrative con-
27 tractors”; and

28 (iii) by striking subparagraphs (D) and (E);

29 (C) in paragraph (3)—

30 (i) in the matter before subparagraph (A), by
31 striking “Each such contract shall provide that the
32 carrier” and inserting “The Secretary”;

33 (ii) by striking “will” the first place it appears
34 in each of subparagraphs (A), (B), (F), (G), (H),
35 and (L) and inserting “shall”;

36 (iii) in subparagraph (B), in the matter before
37 clause (i), by striking “to the policyholders and

1 subscribers of the carrier” and inserting “to the
2 policyholders and subscribers of the medicare ad-
3 ministrative contractor”;

4 (iv) by striking subparagraphs (C), (D), and
5 (E);

6 (v) in subparagraph (H)—

7 (I) by striking “if it makes determinations
8 or payments with respect to physicians’ serv-
9 ices,” in the matter preceding clause (i); and

10 (II) by striking “carrier” and inserting
11 “medicare administrative contractor” in clause
12 (i);

13 (vi) by striking subparagraph (I);

14 (vii) in subparagraph (L), by striking the
15 semicolon and inserting a period;

16 (viii) in the first sentence, after subparagraph
17 (L), by striking “and shall contain” and all that
18 follows through the period; and

19 (ix) in the seventh sentence, by inserting
20 “medicare administrative contractor,” after “car-
21 rier,”; and

22 (D) by striking paragraph (5);

23 (E) in paragraph (6)(D)(iv), by striking “carrier”
24 and inserting “medicare administrative contractor”;
25 and

26 (F) in paragraph (7), by striking “the carrier”
27 and inserting “the Secretary” each place it appears.

28 (4) Subsection (c) is amended—

29 (A) by striking paragraph (1);

30 (B) in paragraph (2)(A), by striking “contract
31 under this section which provides for the disbursement
32 of funds, as described in subsection (a)(1)(B),” and in-
33 serting “contract under section 1874A that provides for
34 making payments under this part”;

35 (C) in paragraph (3)(A), by striking “subsection
36 (a)(1)(B)” and inserting “section 1874A(a)(3)(B)”;

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(D) in paragraph (4), in the matter preceding subparagraph (A), by striking “carrier” and inserting “medicare administrative contractor”; and

(E) by striking paragraphs (5) and (6).

(5) Subsections (d), (e), and (f) are repealed.

(6) Subsection (g) is amended by striking “carrier or carriers” and inserting “medicare administrative contractor or contractors”.

(7) Subsection (h) is amended—

(A) in paragraph (2)—

(i) by striking “Each carrier having an agreement with the Secretary under subsection (a)” and inserting “The Secretary”; and

(ii) by striking “Each such carrier” and inserting “The Secretary”;

(B) in paragraph (3)(A)—

(i) by striking “a carrier having an agreement with the Secretary under subsection (a)” and inserting “medicare administrative contractor having a contract under section 1874A that provides for making payments under this part”; and

(ii) by striking “such carrier” and inserting “such contractor”;

(C) in paragraph (3)(B)—

(i) by striking “a carrier” and inserting “a medicare administrative contractor” each place it appears; and

(ii) by striking “the carrier” and inserting “the contractor” each place it appears; and

(D) in paragraphs (5)(A) and (5)(B)(iii), by striking “carriers” and inserting “medicare administrative contractors” each place it appears.

(8) Subsection (l) is amended—

(A) in paragraph (1)(A)(iii), by striking “carrier” and inserting “medicare administrative contractor”; and

1 (B) in paragraph (2), by striking “carrier” and in-
2 serting “medicare administrative contractor”.

3 (9) Subsection (p)(3)(A) is amended by striking “car-
4 rier” and inserting “medicare administrative contractor”.

5 (10) Subsection (q)(1)(A) is amended by striking “car-
6 rier”.

7 (d) EFFECTIVE DATE; TRANSITION RULE.—

8 (1) EFFECTIVE DATE.—

9 (A) IN GENERAL.—Except as otherwise provided
10 in this subsection, the amendments made by this sec-
11 tion shall take effect on October 1, 2005, and the Sec-
12 retary is authorized to take such steps before such date
13 as may be necessary to implement such amendments on
14 a timely basis.

15 (B) CONSTRUCTION FOR CURRENT CONTRACTS.—
16 Such amendments shall not apply to contracts in effect
17 before the date specified under subparagraph (A) that
18 continue to retain the terms and conditions in effect on
19 such date (except as otherwise provided under this Act,
20 other than under this section) until such date as the
21 contract is let out for competitive bidding under such
22 amendments.

23 (C) DEADLINE FOR COMPETITIVE BIDDING.—The
24 Secretary shall provide for the letting by competitive
25 bidding of all contracts for functions of medicare ad-
26 ministrative contractors for annual contract periods
27 that begin on or after October 1, 2010.

28 (D) WAIVER OF PROVIDER NOMINATION PROVI-
29 SIONS DURING TRANSITION.—During the period begin-
30 ning on the date of the enactment of this Act and be-
31 fore the date specified under subparagraph (A), the
32 Secretary may enter into new agreements under section
33 1816 of the Social Security Act (42 U.S.C. 1395h)
34 without regard to any of the provider nomination provi-
35 sions of such section.

36 (2) GENERAL TRANSITION RULES.—The Secretary
37 shall take such steps, consistent with paragraph (1)(B) and

1 (1)(C), as are necessary to provide for an appropriate tran-
2 sition from contracts under section 1816 and section 1842
3 of the Social Security Act (42 U.S.C. 1395h, 1395u) to
4 contracts under section 1874A, as added by subsection
5 (a)(1).

6 (3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS
7 UNDER CURRENT CONTRACTS AND AGREEMENTS AND
8 UNDER ROLLOVER CONTRACTS.—The provisions contained
9 in the exception in section 1893(d)(2) of the Social Secu-
10 rity Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply
11 notwithstanding the amendments made by this section, and
12 any reference in such provisions to an agreement or con-
13 tract shall be deemed to include a contract under section
14 1874A of such Act, as inserted by subsection (a)(1), that
15 continues the activities referred to in such provisions.

16 (e) REFERENCES.—On and after the effective date pro-
17 vided under subsection (d)(1), any reference to a fiscal inter-
18 mediary or carrier under title XI or XVIII of the Social Secu-
19 rity Act (or any regulation, manual instruction, interpretative
20 rule, statement of policy, or guideline issued to carry out such
21 titles) shall be deemed a reference to a medicare administrative
22 contractor (as provided under section 1874A of the Social Se-
23 curity Act).

24 (f) REPORTS ON IMPLEMENTATION.—

25 (1) PLAN FOR IMPLEMENTATION.—By not later than
26 October 1, 2004, the Secretary shall submit a report to
27 Congress and the Comptroller General of the United States
28 that describes the plan for implementation of the amend-
29 ments made by this section. The Comptroller General shall
30 conduct an evaluation of such plan and shall submit to
31 Congress, not later than 6 months after the date the report
32 is received, a report on such evaluation and shall include
33 in such report such recommendations as the Comptroller
34 General deems appropriate.

35 (2) STATUS OF IMPLEMENTATION.—The Secretary
36 shall submit a report to Congress not later than October
37 1, 2008, that describes the status of implementation of

1 such amendments and that includes a description of the
2 following:

3 (A) The number of contracts that have been com-
4 petitively bid as of such date.

5 (B) The distribution of functions among contracts
6 and contractors.

7 (C) A timeline for complete transition to full com-
8 petition.

9 (D) A detailed description of how the Secretary
10 has modified oversight and management of medicare
11 contractors to adapt to full competition.

12 **SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY**
13 **FOR MEDICARE ADMINISTRATIVE CONTRAC-**
14 **TORS.**

15 (a) IN GENERAL.—Section 1874A, as added by section
16 911(a)(1), is amended by adding at the end the following new
17 subsection:

18 “(e) REQUIREMENTS FOR INFORMATION SECURITY.—

19 “(1) DEVELOPMENT OF INFORMATION SECURITY PRO-
20 GRAM.—A medicare administrative contractor that per-
21 forms the functions referred to in subparagraphs (A) and
22 (B) of subsection (a)(4) (relating to determining and mak-
23 ing payments) shall implement a contractor-wide informa-
24 tion security program to provide information security for
25 the operation and assets of the contractor with respect to
26 such functions under this title. An information security
27 program under this paragraph shall meet the requirements
28 for information security programs imposed on Federal
29 agencies under paragraphs (1) through (8) of section
30 3544(b) of title 44, United States Code (other than the re-
31 quirements under paragraphs (2)(D)(i), (5)(A), and (5)(B)
32 of such section).

33 “(2) INDEPENDENT AUDITS.—

34 “(A) PERFORMANCE OF ANNUAL EVALUATIONS.—

35 Each year a medicare administrative contractor that
36 performs the functions referred to in subparagraphs
37 (A) and (B) of subsection (a)(4) (relating to deter-

1 mining and making payments) shall undergo an evalua-
2 tion of the information security of the contractor with
3 respect to such functions under this title. The evalua-
4 tion shall—

5 “(i) be performed by an entity that meets such
6 requirements for independence as the Inspector
7 General of the Department of Health and Human
8 Services may establish; and

9 “(ii) test the effectiveness of information secu-
10 rity control techniques of an appropriate subset of
11 the contractor’s information systems (as defined in
12 section 3502(8) of title 44, United States Code) re-
13 lating to such functions under this title and an as-
14 sessment of compliance with the requirements of
15 this subsection and related information security
16 policies, procedures, standards and guidelines, in-
17 cluding policies and procedures as may be pre-
18 scribed by the Director of the Office of Manage-
19 ment and Budget and applicable information secu-
20 rity standards promulgated under section 11331 of
21 title 40, United States Code.

22 “(B) DEADLINE FOR INITIAL EVALUATION.—

23 “(i) NEW CONTRACTORS.—In the case of a
24 medicare administrative contractor covered by this
25 subsection that has not previously performed the
26 functions referred to in subparagraphs (A) and (B)
27 of subsection (a)(4) (relating to determining and
28 making payments) as a fiscal intermediary or car-
29 rier under section 1816 or 1842, the first inde-
30 pendent evaluation conducted pursuant subpara-
31 graph (A) shall be completed prior to commencing
32 such functions.

33 “(ii) OTHER CONTRACTORS.—In the case of a
34 medicare administrative contractor covered by this
35 subsection that is not described in clause (i), the
36 first independent evaluation conducted pursuant
37 subparagraph (A) shall be completed within 1 year

1 after the date the contractor commences functions
2 referred to in clause (i) under this section.

3 “(C) REPORTS ON EVALUATIONS.—

4 “(i) TO THE DEPARTMENT OF HEALTH AND
5 HUMAN SERVICES.—The results of independent
6 evaluations under subparagraph (A) shall be sub-
7 mitted promptly to the Inspector General of the
8 Department of Health and Human Services and to
9 the Secretary.

10 “(ii) TO CONGRESS.—The Inspector General
11 of Department of Health and Human Services shall
12 submit to Congress annual reports on the results of
13 such evaluations, including assessments of the
14 scope and sufficiency of such evaluations.

15 “(iii) AGENCY REPORTING.—The Secretary
16 shall address the results of such evaluations in re-
17 ports required under section 3544(c) of title 44,
18 United States Code.”.

19 (b) APPLICATION OF REQUIREMENTS TO FISCAL INTER-
20 MEDIARIES AND CARRIERS.—

21 (1) IN GENERAL.—The provisions of section
22 1874A(e)(2) of the Social Security Act (other than sub-
23 paragraph (B)), as added by subsection (a), shall apply to
24 each fiscal intermediary under section 1816 of the Social
25 Security Act (42 U.S.C. 1395h) and each carrier under
26 section 1842 of such Act (42 U.S.C. 1395u) in the same
27 manner as they apply to medicare administrative contrac-
28 tors under such provisions.

29 (2) DEADLINE FOR INITIAL EVALUATION.—In the case
30 of such a fiscal intermediary or carrier with an agreement
31 or contract under such respective section in effect as of the
32 date of the enactment of this Act, the first evaluation
33 under section 1874A(e)(2)(A) of the Social Security Act
34 (as added by subsection (a)), pursuant to paragraph (1),
35 shall be completed (and a report on the evaluation sub-
36 mitted to the Secretary) by not later than 1 year after such
37 date.

Subtitle C—Education and Outreach

SEC. 921. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1888 the following new section:

“PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

“SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

(3) REPORT.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the funding of provider education under section 1889(a) of the Social Security Act, as added by paragraph (1).

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a), is amended by adding at the end the following new subsection:

“(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—The Secretary shall use specific claims payment error rates or similar methodology of medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.”.

(2) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(f) of the Social Security Act, as added by paragraph (1), shall apply

1 to each fiscal intermediary under section 1816 of the Social
2 Security Act (42 U.S.C. 1395h) and each carrier under
3 section 1842 of such Act (42 U.S.C. 1395u) in the same
4 manner as they apply to medicare administrative contrac-
5 tors under such provisions.

6 (3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—
7 Not later than October 1, 2004, the Comptroller General
8 of the United States shall submit to Congress and to the
9 Secretary a report on the adequacy of the methodology
10 under section 1874A(f) of the Social Security Act, as added
11 by paragraph (1), and shall include in the report such rec-
12 ommendations as the Comptroller General determines ap-
13 propriate with respect to the methodology.

14 (4) REPORT ON USE OF METHODOLOGY IN ASSESSING
15 CONTRACTOR PERFORMANCE.—Not later than October 1,
16 2004, the Secretary shall submit to Congress a report that
17 describes how the Secretary intends to use such method-
18 ology in assessing medicare contractor performance in im-
19 plementing effective education and outreach programs, in-
20 cluding whether to use such methodology as a basis for per-
21 formance bonuses. The report shall include an analysis of
22 the sources of identified errors and potential changes in
23 systems of contractors and rules of the Secretary that could
24 reduce claims error rates.

25 (c) PROVISION OF ACCESS TO AND PROMPT RESPONSES
26 FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

27 (1) IN GENERAL.—Section 1874A, as added by section
28 911(a)(1) and as amended by section 912(a) and sub-
29 section (b), is further amended by adding at the end the
30 following new subsection:

31 “(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS
32 OF SERVICES AND SUPPLIERS.—

33 “(1) COMMUNICATION STRATEGY.—The Secretary
34 shall develop a strategy for communications with individ-
35 uals entitled to benefits under part A or enrolled under
36 part B, or both, and with providers of services and sup-
37 pliers under this title.

1 “(2) RESPONSE TO WRITTEN INQUIRIES.—Each medi-
2 care administrative contractor shall, for those providers of
3 services and suppliers which submit claims to the con-
4 tractor for claims processing and for those individuals enti-
5 tled to benefits under part A or enrolled under part B, or
6 both, with respect to whom claims are submitted for claims
7 processing, provide general written responses (which may
8 be through electronic transmission) in a clear, concise, and
9 accurate manner to inquiries of providers of services, sup-
10 pliers and individuals entitled to benefits under part A or
11 enrolled under part B, or both, concerning the programs
12 under this title within 45 business days of the date of re-
13 ceipt of such inquiries.

14 “(3) RESPONSE TO TOLL-FREE LINES.—The Secretary
15 shall ensure that each medicare administrative contractor
16 shall provide, for those providers of services and suppliers
17 which submit claims to the contractor for claims processing
18 and for those individuals entitled to benefits under part A
19 or enrolled under part B, or both, with respect to whom
20 claims are submitted for claims processing, a toll-free tele-
21 phone number at which such individuals, providers of serv-
22 ices and suppliers may obtain information regarding billing,
23 coding, claims, coverage, and other appropriate information
24 under this title.

25 “(4) MONITORING OF CONTRACTOR RESPONSES.—

26 “(A) IN GENERAL.—Each medicare administrative
27 contractor shall, consistent with standards developed by
28 the Secretary under subparagraph (B)—

29 “(i) maintain a system for identifying who
30 provides the information referred to in paragraphs
31 (2) and (3); and

32 “(ii) monitor the accuracy, consistency, and
33 timeliness of the information so provided.

34 “(B) DEVELOPMENT OF STANDARDS.—

35 “(i) IN GENERAL.—The Secretary shall estab-
36 lish and make public standards to monitor the ac-
37 curacy, consistency, and timeliness of the informa-

tion provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

“(ii) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

“(C) DIRECT MONITORING.—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect October 1, 2004.

(3) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(g) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

(1) IN GENERAL.—Section 1889, as added by subsection (a), is amended by adding at the end the following new subsections:

“(b) ENHANCED EDUCATION AND TRAINING.—

“(1) ADDITIONAL RESOURCES.—There are authorized to be appropriated to the Secretary (in appropriate part

1 from the Federal Hospital Insurance Trust Fund and the
2 Federal Supplementary Medical Insurance Trust Fund)
3 \$25,000,000 for each of fiscal years 2005 and 2006 and
4 such sums as may be necessary for succeeding fiscal years.

5 “(2) USE.—The funds made available under para-
6 graph (1) shall be used to increase the conduct by medicare
7 contractors of education and training of providers of serv-
8 ices and suppliers regarding billing, coding, and other ap-
9 propriate items and may also be used to improve the accu-
10 racy, consistency, and timeliness of contractor responses.

11 “(c) TAILORING EDUCATION AND TRAINING ACTIVITIES
12 FOR SMALL PROVIDERS OR SUPPLIERS.—

13 “(1) IN GENERAL.—Insofar as a medicare contractor
14 conducts education and training activities, it shall tailor
15 such activities to meet the special needs of small providers
16 of services or suppliers (as defined in paragraph (2)).

17 “(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—
18 In this subsection, the term ‘small provider of services or
19 supplier’ means—

20 “(A) a provider of services with fewer than 25 full-
21 time-equivalent employees; or

22 “(B) a supplier with fewer than 10 full-time-equiv-
23 alent employees.”.

24 (2) EFFECTIVE DATE.—The amendment made by
25 paragraph (1) shall take effect on October 1, 2004.

26 (e) REQUIREMENT TO MAINTAIN INTERNET SITES.—

27 (1) IN GENERAL.—Section 1889, as added by sub-
28 section (a) and as amended by subsection (d), is further
29 amended by adding at the end the following new sub-
30 section:

31 “(d) INTERNET SITES; FAQs.—The Secretary, and each
32 medicare contractor insofar as it provides services (including
33 claims processing) for providers of services or suppliers, shall
34 maintain an Internet site which—

35 “(1) provides answers in an easily accessible format to
36 frequently asked questions, and

1 “(2) includes other published materials of the con-
2 tractor,
3 that relate to providers of services and suppliers under the pro-
4 grams under this title (and title XI insofar as it relates to such
5 programs).”.

6 (2) EFFECTIVE DATE.—The amendment made by
7 paragraph (1) shall take effect on October 1, 2004.

8 (f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

9 (1) IN GENERAL.—Section 1889, as added by sub-
10 section (a) and as amended by subsections (d) and (e), is
11 further amended by adding at the end the following new
12 subsections:

13 “(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION
14 PROGRAM ACTIVITIES.—A medicare contractor may not use a
15 record of attendance at (or failure to attend) educational activi-
16 ties or other information gathered during an educational pro-
17 gram conducted under this section or otherwise by the Sec-
18 retary to select or track providers of services or suppliers for
19 the purpose of conducting any type of audit or prepayment re-
20 view.

21 “(f) CONSTRUCTION.—Nothing in this section or section
22 1893(g) shall be construed as providing for disclosure by a
23 medicare contractor of information that would compromise
24 pending law enforcement activities or reveal findings of law en-
25 forcement-related audits.

26 “(g) DEFINITIONS.—For purposes of this section, the
27 term ‘medicare contractor’ includes the following:

28 “(1) A medicare administrative contractor with a con-
29 tract under section 1874A, including a fiscal intermediary
30 with a contract under section 1816 and a carrier with a
31 contract under section 1842.

32 “(2) An eligible entity with a contract under section
33 1893.

34 Such term does not include, with respect to activities of a spe-
35 cific provider of services or supplier an entity that has no au-
36 thority under this title or title IX with respect to such activities
37 and such provider of services or supplier.”.

1 (2) EFFECTIVE DATE.—The amendment made by
2 paragraph (1) shall take effect on the date of the enact-
3 ment of this Act.

4 **SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE**
5 **DEMONSTRATION PROGRAM.**

6 (a) ESTABLISHMENT.—

7 (1) IN GENERAL.—The Secretary shall establish a
8 demonstration program (in this section referred to as the
9 “demonstration program”) under which technical assist-
10 ance described in paragraph (2) is made available, upon re-
11 quest and on a voluntary basis, to small providers of serv-
12 ices or suppliers in order to improve compliance with the
13 applicable requirements of the programs under medicare
14 program under title XVIII of the Social Security Act (in-
15 cluding provisions of title XI of such Act insofar as they
16 relate to such title and are not administered by the Office
17 of the Inspector General of the Department of Health and
18 Human Services).

19 (2) FORMS OF TECHNICAL ASSISTANCE.—The tech-
20 nical assistance described in this paragraph is—

21 (A) evaluation and recommendations regarding
22 billing and related systems; and

23 (B) information and assistance regarding policies
24 and procedures under the medicare program, including
25 coding and reimbursement.

26 (3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—
27 In this section, the term “small providers of services or
28 suppliers” means—

29 (A) a provider of services with fewer than 25 full-
30 time-equivalent employees; or

31 (B) a supplier with fewer than 10 full-time-equa-
32 lent employees.

33 (b) QUALIFICATION OF CONTRACTORS.—In conducting the
34 demonstration program, the Secretary shall enter into contracts
35 with qualified organizations (such as peer review organizations
36 or entities described in section 1889(g)(2) of the Social Secu-
37 rity Act, as inserted by section 5(f)(1)) with appropriate exper-

1 tise with billing systems of the full range of providers of serv-
2 ices and suppliers to provide the technical assistance. In award-
3 ing such contracts, the Secretary shall consider any prior inves-
4 tigations of the entity's work by the Inspector General of De-
5 partment of Health and Human Services or the Comptroller
6 General of the United States.

7 (c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The tech-
8 nical assistance provided under the demonstration program
9 shall include a direct and in-person examination of billing sys-
10 tems and internal controls of small providers of services or sup-
11 pliers to determine program compliance and to suggest more
12 efficient or effective means of achieving such compliance.

13 (d) AVOIDANCE OF RECOVERY ACTIONS FOR PROBLEMS
14 IDENTIFIED AS CORRECTED.—The Secretary shall provide
15 that, absent evidence of fraud and notwithstanding any other
16 provision of law, any errors found in a compliance review for
17 a small provider of services or supplier that participates in the
18 demonstration program shall not be subject to recovery action
19 if the technical assistance personnel under the program deter-
20 mine that—

21 (1) the problem that is the subject of the compliance
22 review has been corrected to their satisfaction within 30
23 days of the date of the visit by such personnel to the small
24 provider of services or supplier; and

25 (2) such problem remains corrected for such period as
26 is appropriate.

27 The previous sentence applies only to claims filed as part of the
28 demonstration program and lasts only for the duration of such
29 program and only as long as the small provider of services or
30 supplier is a participant in such program.

31 (e) GAO EVALUATION.—Not later than 2 years after the
32 date of the date the demonstration program is first imple-
33 mented, the Comptroller General, in consultation with the In-
34 spector General of the Department of Health and Human Serv-
35 ices, shall conduct an evaluation of the demonstration program.
36 The evaluation shall include a determination of whether claims
37 error rates are reduced for small providers of services or sup-

1 pliers who participated in the program and the extent of im-
2 proper payments made as a result of the demonstration pro-
3 gram. The Comptroller General shall submit a report to the
4 Secretary and the Congress on such evaluation and shall in-
5 clude in such report recommendations regarding the continu-
6 ation or extension of the demonstration program.

7 (f) FINANCIAL PARTICIPATION BY PROVIDERS.—The pro-
8 vision of technical assistance to a small provider of services or
9 supplier under the demonstration program is conditioned upon
10 the small provider of services or supplier paying an amount es-
11 timated (and disclosed in advance of a provider's or supplier's
12 participation in the program) to be equal to 25 percent of the
13 cost of the technical assistance.

14 (g) AUTHORIZATION OF APPROPRIATIONS.—There are au-
15 thorized to be appropriated to the Secretary (in appropriate
16 part from the Federal Hospital Insurance Trust Fund and the
17 Federal Supplementary Medical Insurance Trust Fund) to
18 carry out the demonstration program—

19 (1) for fiscal year 2005, \$1,000,000, and

20 (2) for fiscal year 2006, \$6,000,000.

21 **SEC. 923. MEDICARE PROVIDER OMBUDSMAN; MEDI-**
22 **CARE BENEFICIARY OMBUDSMAN.**

23 (a) MEDICARE PROVIDER OMBUDSMAN.—Section 1868
24 (42 U.S.C. 1395ee) is amended—

25 (1) by adding at the end of the heading the following:

26 “; MEDICARE PROVIDER OMBUDSMAN”;

27 (2) by inserting “PRACTICING PHYSICIANS ADVISORY
28 COUNCIL.—(1)” after “(a)”;

29 (3) in paragraph (1), as so redesignated under para-
30 graph (2), by striking “in this section” and inserting “in
31 this subsection”;

32 (4) by redesignating subsections (b) and (c) as para-
33 graphs (2) and (3), respectively; and

34 (5) by adding at the end the following new subsection:

35 “(b) MEDICARE PROVIDER OMBUDSMAN.—The Secretary
36 shall appoint within the Department of Health and Human

1 Services a Medicare Provider Ombudsman. The Ombudsman
2 shall—

3 “(1) provide assistance, on a confidential basis, to pro-
4 viders of services and suppliers with respect to complaints,
5 grievances, and requests for information concerning the
6 programs under this title (including provisions of title XI
7 insofar as they relate to this title and are not administered
8 by the Office of the Inspector General of the Department
9 of Health and Human Services) and in the resolution of
10 unclear or conflicting guidance given by the Secretary and
11 medicare contractors to such providers of services and sup-
12 pliers regarding such programs and provisions and require-
13 ments under this title and such provisions; and

14 “(2) submit recommendations to the Secretary for im-
15 provement in the administration of this title and such pro-
16 visions, including—

17 “(A) recommendations to respond to recurring
18 patterns of confusion in this title and such provisions
19 (including recommendations regarding suspending im-
20 position of sanctions where there is widespread confu-
21 sion in program administration), and

22 “(B) recommendations to provide for an appro-
23 priate and consistent response (including not providing
24 for audits) in cases of self-identified overpayments by
25 providers of services and suppliers.

26 The Ombudsman shall not serve as an advocate for any in-
27 creases in payments or new coverage of services, but may iden-
28 tify issues and problems in payment or coverage policies.”.

29 (b) MEDICARE BENEFICIARY OMBUDSMAN.—Title XVIII,
30 as previously amended, is amended by inserting after section
31 1809 the following new section:

32 “MEDICARE BENEFICIARY OMBUDSMAN

33 “SEC. 1810. (a) IN GENERAL.—The Secretary shall ap-
34 point within the Department of Health and Human Services a
35 Medicare Beneficiary Ombudsman who shall have expertise and
36 experience in the fields of health care and education of (and
37 assistance to) individuals entitled to benefits under this title.

1 “(b) DUTIES.—The Medicare Beneficiary Ombudsman
2 shall—

3 “(1) receive complaints, grievances, and requests for
4 information submitted by individuals entitled to benefits
5 under part A or enrolled under part B, or both, with re-
6 spect to any aspect of the medicare program;

7 “(2) provide assistance with respect to complaints,
8 grievances, and requests referred to in paragraph (1),
9 including—

10 “(A) assistance in collecting relevant information
11 for such individuals, to seek an appeal of a decision or
12 determination made by a fiscal intermediary, carrier,
13 Medicare+ Choice organization, or the Secretary;

14 “(B) assistance to such individuals with any prob-
15 lems arising from disenrollment from a
16 Medicare+ Choice plan under part C; and

17 “(C) assistance to such individuals in presenting
18 information under section 1860D–2(b)(4)(D)(v); and

19 “(3) submit annual reports to Congress and the Sec-
20 retary that describe the activities of the Office and that in-
21 clude such recommendations for improvement in the admin-
22 istration of this title as the Ombudsman determines appro-
23 priate.

24 The Ombudsman shall not serve as an advocate for any in-
25 creases in payments or new coverage of services, but may iden-
26 tify issues and problems in payment or coverage policies.

27 “(c) WORKING WITH HEALTH INSURANCE COUNSELING
28 PROGRAMS.—To the extent possible, the Ombudsman shall
29 work with health insurance counseling programs (receiving
30 funding under section 4360 of Omnibus Budget Reconciliation
31 Act of 1990) to facilitate the provision of information to indi-
32 viduals entitled to benefits under part A or enrolled under part
33 B, or both regarding Medicare+ Choice plans and changes to
34 those plans. Nothing in this subsection shall preclude further
35 collaboration between the Ombudsman and such programs.”.

36 “(c) DEADLINE FOR APPOINTMENT.—The Secretary shall
37 appoint the Medicare Provider Ombudsman and the Medicare

1 Beneficiary Ombudsman, under the amendments made by sub-
2 sections (a) and (b), respectively, by not later than 1 year after
3 the date of the enactment of this Act.

4 (d) FUNDING.—There are authorized to be appropriated to
5 the Secretary (in appropriate part from the Federal Hospital
6 Insurance Trust Fund and the Federal Supplementary Medical
7 Insurance Trust Fund) to carry out the provisions of sub-
8 section (b) of section 1868 of the Social Security Act (relating
9 to the Medicare Provider Ombudsman), as added by subsection
10 (a)(5) and section 1807 of such Act (relating to the Medicare
11 Beneficiary Ombudsman), as added by subsection (b), such
12 sums as are necessary for fiscal year 2004 and each succeeding
13 fiscal year.

14 (e) USE OF CENTRAL, TOLL-FREE NUMBER (1-800-
15 MEDICARE).—

16 (1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE
17 HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—
18 Section 1804(b) (42 U.S.C. 1395b-2(b)) is amended by
19 adding at the end the following: “The Secretary shall pro-
20 vide, through the toll-free number 1-800-MEDICARE, for
21 a means by which individuals seeking information about, or
22 assistance with, such programs who phone such toll-free
23 number are transferred (without charge) to appropriate en-
24 tities for the provision of such information or assistance.
25 Such toll-free number shall be the toll-free number listed
26 for general information and assistance in the annual notice
27 under subsection (a) instead of the listing of numbers of
28 individual contractors.”.

29 (2) MONITORING ACCURACY.—

30 (A) STUDY.—The Comptroller General of the
31 United States shall conduct a study to monitor the ac-
32 curacy and consistency of information provided to indi-
33 viduals entitled to benefits under part A or enrolled
34 under part B, or both, through the toll-free number 1-
35 800-MEDICARE, including an assessment of whether
36 the information provided is sufficient to answer ques-
37 tions of such individuals. In conducting the study, the

1 Comptroller General shall examine the education and
2 training of the individuals providing information
3 through such number.

4 (B) REPORT.—Not later than 1 year after the
5 date of the enactment of this Act, the Comptroller Gen-
6 eral shall submit to Congress a report on the study
7 conducted under subparagraph (A).

8 **SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION**
9 **PROGRAM.**

10 (a) IN GENERAL.—The Secretary shall establish a dem-
11 onstration program (in this section referred to as the “dem-
12 onstration program”) under which medicare specialists em-
13 ployed by the Department of Health and Human Services pro-
14 vide advice and assistance to individuals entitled to benefits
15 under part A of title XVIII of the Social Security Act, or en-
16 rolled under part B of such title, or both, regarding the medi-
17 care program at the location of existing local offices of the So-
18 cial Security Administration.

19 (b) LOCATIONS.—

20 (1) IN GENERAL.—The demonstration program shall
21 be conducted in at least 6 offices or areas. Subject to para-
22 graph (2), in selecting such offices and areas, the Secretary
23 shall provide preference for offices with a high volume of
24 visits by individuals referred to in subsection (a).

25 (2) ASSISTANCE FOR RURAL BENEFICIARIES.—The
26 Secretary shall provide for the selection of at least 2 rural
27 areas to participate in the demonstration program. In con-
28 ducting the demonstration program in such rural areas, the
29 Secretary shall provide for medicare specialists to travel
30 among local offices in a rural area on a scheduled basis.

31 (c) DURATION.—The demonstration program shall be con-
32 ducted over a 3-year period.

33 (d) EVALUATION AND REPORT.—

34 (1) EVALUATION.—The Secretary shall provide for an
35 evaluation of the demonstration program. Such evaluation
36 shall include an analysis of—

1 (A) utilization of, and satisfaction of those individ-
2 uals referred to in subsection (a) with, the assistance
3 provided under the program; and

4 (B) the cost-effectiveness of providing beneficiary
5 assistance through out-stationing medicare specialists
6 at local offices of the Social Security Administration.

7 (2) REPORT.—The Secretary shall submit to Congress
8 a report on such evaluation and shall include in such report
9 recommendations regarding the feasibility of permanently
10 out-stationing medicare specialists at local offices of the So-
11 cial Security Administration.

12 **SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN**
13 **NOTICES TO BENEFICIARIES ABOUT**
14 **SKILLED NURSING FACILITY BENEFITS.**

15 (a) IN GENERAL.—The Secretary shall provide that in
16 medicare beneficiary notices provided (under section 1806(a) of
17 the Social Security Act, 42 U.S.C. 1395b–7(a)) with respect to
18 the provision of post-hospital extended care services under part
19 A of title XVIII of the Social Security Act, there shall be in-
20 cluded information on the number of days of coverage of such
21 services remaining under such part for the medicare beneficiary
22 and spell of illness involved.

23 (b) EFFECTIVE DATE.—Subsection (a) shall apply to no-
24 tices provided during calendar quarters beginning more than 6
25 months after the date of the enactment of this Act.

26 **SEC. 926. INFORMATION ON MEDICARE-CERTIFIED**
27 **SKILLED NURSING FACILITIES IN HOSPITAL**
28 **DISCHARGE PLANS.**

29 (a) AVAILABILITY OF DATA.—The Secretary shall publicly
30 provide information that enables hospital discharge planners,
31 medicare beneficiaries, and the public to identify skilled nursing
32 facilities that are participating in the medicare program.

33 (b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL
34 DISCHARGE PLANS.—

35 (1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C.
36 1395x(ee)(2)(D)) is amended—

(A) by striking “hospice services” and inserting “hospice care and post-hospital extended care services”; and

(B) by inserting before the period at the end the following: “and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides”.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to discharge plans made on or after such date as the Secretary shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a).

Subtitle D—Appeals and Recovery

SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDICAL CARE APPEALS.

(a) TRANSITION PLAN.—

(1) IN GENERAL.—Not later than October 1, 2004, the Commissioner of Social Security and the Secretary shall develop and transmit to Congress and the Comptroller General of the United States a plan under which the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act (and related provisions in title XI of such Act) are transferred from the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Services.

(2) GAO EVALUATION.—The Comptroller General of the United States shall evaluate the plan and, not later than the date that is 6 months after the date on which the plan is received by the Comptroller General, shall submit to Congress a report on such evaluation.

(b) TRANSFER OF ADJUDICATION AUTHORITY.—

(1) IN GENERAL.—Not earlier than July 1, 2005, and not later than October 1, 2005, the Commissioner of Social Security and the Secretary shall implement the transition

1 plan under subsection (a) and transfer the administrative
2 law judge functions described in such subsection from the
3 Social Security Administration to the Secretary.

4 (2) ASSURING INDEPENDENCE OF JUDGES.—The Sec-
5 retary shall assure the independence of administrative law
6 judges performing the administrative law judge functions
7 transferred under paragraph (1) from the Centers for
8 Medicare & Medicaid Services and its contractors. In order
9 to assure such independence, the Secretary shall place such
10 judges in an administrative office that is organizationally
11 and functionally separate from such Centers. Such judges
12 shall report to, and be under the general supervision of, the
13 Secretary, but shall not report to, or be subject to super-
14 vision by, another other officer of the Department.

15 (3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall
16 provide for an appropriate geographic distribution of ad-
17 ministrative law judges performing the administrative law
18 judge functions transferred under paragraph (1) through-
19 out the United States to ensure timely access to such
20 judges.

21 (4) HIRING AUTHORITY.—Subject to the amounts pro-
22 vided in advance in appropriations Act, the Secretary shall
23 have authority to hire administrative law judges to hear
24 such cases, giving priority to those judges with prior experi-
25 ence in handling medicare appeals and in a manner con-
26 sistent with paragraph (3), and to hire support staff for
27 such judges.

28 (5) FINANCING.—Amounts payable under law to the
29 Commissioner for administrative law judges performing the
30 administrative law judge functions transferred under para-
31 graph (1) from the Federal Hospital Insurance Trust Fund
32 and the Federal Supplementary Medical Insurance Trust
33 Fund shall become payable to the Secretary for the func-
34 tions so transferred.

35 (6) SHARED RESOURCES.—The Secretary shall enter
36 into such arrangements with the Commissioner as may be
37 appropriate with respect to transferred functions of admin-

1 istrative law judges to share office space, support staff, and
2 other resources, with appropriate reimbursement from the
3 Trust Funds described in paragraph (5).

4 (c) INCREASED FINANCIAL SUPPORT.—In addition to any
5 amounts otherwise appropriated, to ensure timely action on ap-
6 peals before administrative law judges and the Departmental
7 Appeals Board consistent with section 1869 of the Social Secu-
8 rity Act (as amended by section 521 of BIPA, 114 Stat.
9 2763A–534), there are authorized to be appropriated (in appro-
10 priate part from the Federal Hospital Insurance Trust Fund
11 and the Federal Supplementary Medical Insurance Trust
12 Fund) to the Secretary such sums as are necessary for fiscal
13 year 2005 and each subsequent fiscal year to—

14 (1) increase the number of administrative law judges
15 (and their staffs) under subsection (b)(4);

16 (2) improve education and training opportunities for
17 administrative law judges (and their staffs); and

18 (3) increase the staff of the Departmental Appeals
19 Board.

20 (d) CONFORMING AMENDMENT.—Section 1869(f)(2)(A)(i)
21 (42 U.S.C. 1395ff(f)(2)(A)(i)), as added by section 522(a) of
22 BIPA (114 Stat. 2763A–543), is amended by striking “of the
23 Social Security Administration”.

24 **SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.**

25 (a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—Section
26 1869(b) (42 U.S.C. 1395ff(b)) as amended by BIPA, is
27 amended—

28 (1) in paragraph (1)(A), by inserting “, subject to
29 paragraph (2),” before “to judicial review of the Sec-
30 retary’s final decision”;

31 (2) in paragraph (1)(F)—

32 (A) by striking clause (ii);

33 (B) by striking “PROCEEDING” and all that follows
34 through “DETERMINATION” and inserting “DETER-
35 MINATIONS AND RECONSIDERATIONS”; and

36 (C) by redesignating subclauses (I) and (II) as
37 clauses (i) and (ii) and by moving the indentation of

1 such subclauses (and the matter that follows) 2 ems to
2 the left; and

3 (3) by adding at the end the following new paragraph:

4 “(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

5 “(A) IN GENERAL.—The Secretary shall establish
6 a process under which a provider of services or supplier
7 that furnishes an item or service or an individual enti-
8 tled to benefits under part A or enrolled under part B,
9 or both, who has filed an appeal under paragraph (1)
10 may obtain access to judicial review when a review
11 panel (described in subparagraph (D)), on its own mo-
12 tion or at the request of the appellant, determines that
13 no entity in the administrative appeals process has the
14 authority to decide the question of law or regulation
15 relevant to the matters in controversy and that there
16 is no material issue of fact in dispute. The appellant
17 may make such request only once with respect to a
18 question of law or regulation in a case of an appeal.

19 “(B) PROMPT DETERMINATIONS.—If, after or co-
20 incident with appropriately filing a request for an ad-
21 ministrative hearing, the appellant requests a deter-
22 mination by the appropriate review panel that no re-
23 view panel has the authority to decide the question of
24 law or regulations relevant to the matters in con-
25 troversy and that there is no material issue of fact in
26 dispute and if such request is accompanied by the doc-
27 uments and materials as the appropriate review panel
28 shall require for purposes of making such determina-
29 tion, such review panel shall make a determination on
30 the request in writing within 60 days after the date
31 such review panel receives the request and such accom-
32 panying documents and materials. Such a determina-
33 tion by such review panel shall be considered a final de-
34 cision and not subject to review by the Secretary.

35 “(C) ACCESS TO JUDICIAL REVIEW.—

36 “(i) IN GENERAL.—If the appropriate review
37 panel—

1 “(I) determines that there are no material
2 issues of fact in dispute and that the only issue
3 is one of law or regulation that no review panel
4 has the authority to decide; or

5 “(II) fails to make such determination
6 within the period provided under subparagraph
7 (B);

8 then the appellant may bring a civil action as de-
9 scribed in this subparagraph.

10 “(ii) DEADLINE FOR FILING.—Such action
11 shall be filed, in the case described in—

12 “(I) clause (i)(I), within 60 days of date
13 of the determination described in such subpara-
14 graph; or

15 “(II) clause (i)(II), within 60 days of the
16 end of the period provided under subparagraph
17 (B) for the determination.

18 “(iii) VENUE.—Such action shall be brought
19 in the district court of the United States for the ju-
20 dicial district in which the appellant is located (or,
21 in the case of an action brought jointly by more
22 than one applicant, the judicial district in which
23 the greatest number of applicants are located) or in
24 the district court for the District of Columbia.

25 “(iv) INTEREST ON AMOUNTS IN CON-
26 TROVERSY.—Where a provider of services or sup-
27 plier seeks judicial review pursuant to this para-
28 graph, the amount in controversy shall be subject
29 to annual interest beginning on the first day of the
30 first month beginning after the 60-day period as
31 determined pursuant to clause (ii) and equal to the
32 rate of interest on obligations issued for purchase
33 by the Federal Hospital Insurance Trust Fund and
34 by the Federal Supplementary Medical Insurance
35 Trust Fund for the month in which the civil action
36 authorized under this paragraph is commenced, to
37 be awarded by the reviewing court in favor of the

1 prevailing party. No interest awarded pursuant to
2 the preceding sentence shall be deemed income or
3 cost for the purposes of determining reimbursement
4 due providers of services or suppliers under this
5 Act.

6 “(D) REVIEW PANELS.—For purposes of this sub-
7 section, a ‘review panel’ is a panel consisting of 3 mem-
8 bers (who shall be administrative law judges, members
9 of the Departmental Appeals Board, or qualified indi-
10 viduals associated with a qualified independent con-
11 tractor (as defined in subsection (c)(2)) or with another
12 independent entity) designated by the Secretary for
13 purposes of making determinations under this para-
14 graph.”.

15 (b) APPLICATION TO PROVIDER AGREEMENT DETERMINA-
16 TIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is
17 amended—

18 (1) by inserting “(A)” after “(h)(1)”; and

19 (2) by adding at the end the following new subpara-
20 graph:

21 “(B) An institution or agency described in subparagraph
22 (A) that has filed for a hearing under subparagraph (A) shall
23 have expedited access to judicial review under this subpara-
24 graph in the same manner as providers of services, suppliers,
25 and individuals entitled to benefits under part A or enrolled
26 under part B, or both, may obtain expedited access to judicial
27 review under the process established under section 1869(b)(2).
28 Nothing in this subparagraph shall be construed to affect the
29 application of any remedy imposed under section 1819 during
30 the pendency of an appeal under this subparagraph.”.

31 (c) EFFECTIVE DATE.—The amendments made by this
32 section shall apply to appeals filed on or after October 1, 2004.

33 (d) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREE-
34 MENT DETERMINATIONS.—

35 (1) TERMINATION AND CERTAIN OTHER IMMEDIATE
36 REMEDIES.—The Secretary shall develop and implement a
37 process to expedite proceedings under sections 1866(h) of

1 the Social Security Act (42 U.S.C. 1395cc(h)) in which the
2 remedy of termination of participation, or a remedy de-
3 scribed in clause (i) or (iii) of section 1819(h)(2)(B) of
4 such Act (42 U.S.C. 1395i-3(h)(2)(B)) which is applied on
5 an immediate basis, has been imposed. Under such process
6 priority shall be provided in cases of termination.

7 (2) INCREASED FINANCIAL SUPPORT.—In addition to
8 any amounts otherwise appropriated, to reduce by 50 per-
9 cent the average time for administrative determinations on
10 appeals under section 1866(h) of the Social Security Act
11 (42 U.S.C. 1395cc(h)), there are authorized to be appro-
12 priated (in appropriate part from the Federal Hospital In-
13 surance Trust Fund and the Federal Supplementary Med-
14 ical Insurance Trust Fund) to the Secretary such addi-
15 tional sums for fiscal year 2005 and each subsequent fiscal
16 year as may be necessary. The purposes for which such
17 amounts are available include increasing the number of ad-
18 ministrative law judges (and their staffs) and the appellate
19 level staff at the Departmental Appeals Board of the De-
20 partment of Health and Human Services and educating
21 such judges and staffs on long-term care issues.

22 **SEC. 933. REVISIONS TO MEDICARE APPEALS PROCESS.**

23 (a) REQUIRING FULL AND EARLY PRESENTATION OF EVI-
24 DENCE.—

25 (1) IN GENERAL.—Section 1869(b) (42 U.S.C.
26 1395ff(b)), as amended by BIPA and as amended by sec-
27 tion 932(a), is further amended by adding at the end the
28 following new paragraph:

29 “(3) REQUIRING FULL AND EARLY PRESENTATION OF
30 EVIDENCE BY PROVIDERS.—A provider of services or sup-
31 plier may not introduce evidence in any appeal under this
32 section that was not presented at the reconsideration con-
33 ducted by the qualified independent contractor under sub-
34 section (c), unless there is good cause which precluded the
35 introduction of such evidence at or before that reconsider-
36 ation.”.

1 (2) EFFECTIVE DATE.—The amendment made by
2 paragraph (1) shall take effect on October 1, 2004.

3 (b) USE OF PATIENTS' MEDICAL RECORDS.—Section
4 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)), as amended
5 by BIPA, is amended by inserting “(including the medical
6 records of the individual involved)” after “clinical experience”.

7 (c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

8 (1) INITIAL DETERMINATIONS AND REDETERMINA-
9 TIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)), as amend-
10 ed by BIPA, is amended by adding at the end the following
11 new paragraphs:

12 “(4) REQUIREMENTS OF NOTICE OF DETERMINA-
13 TIONS.—With respect to an initial determination insofar as
14 it results in a denial of a claim for benefits—

15 “(A) the written notice on the determination shall
16 include—

17 “(i) the reasons for the determination, includ-
18 ing whether a local medical review policy or a local
19 coverage determination was used;

20 “(ii) the procedures for obtaining additional
21 information concerning the determination, includ-
22 ing the information described in subparagraph (B);
23 and

24 “(iii) notification of the right to seek a rede-
25 termination or otherwise appeal the determination
26 and instructions on how to initiate such a redeter-
27 mination under this section; and

28 “(B) the person provided such notice may obtain,
29 upon request, the specific provision of the policy, man-
30 ual, or regulation used in making the determination.

31 “(5) REQUIREMENTS OF NOTICE OF REDETERMINA-
32 TIONS.—With respect to a redetermination insofar as it re-
33 sults in a denial of a claim for benefits—

34 “(A) the written notice on the redetermination
35 shall include—

36 “(i) the specific reasons for the redetermina-
37 tion;

1 “(ii) as appropriate, a summary of the clinical
2 or scientific evidence used in making the redeter-
3 mination;

4 “(iii) a description of the procedures for ob-
5 taining additional information concerning the rede-
6 termination; and

7 “(iv) notification of the right to appeal the re-
8 determination and instructions on how to initiate
9 such an appeal under this section;

10 “(B) such written notice shall be provided in
11 printed form and written in a manner calculated to be
12 understood by the individual entitled to benefits under
13 part A or enrolled under part B, or both; and

14 “(C) the person provided such notice may obtain,
15 upon request, information on the specific provision of
16 the policy, manual, or regulation used in making the
17 redetermination.”.

18 (2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42
19 U.S.C. 1395ff(c)(3)(E)), as amended by BIPA, is
20 amended—

21 (A) by inserting “be written in a manner cal-
22 culated to be understood by the individual entitled to
23 benefits under part A or enrolled under part B, or
24 both, and shall include (to the extent appropriate)”
25 after “in writing, ”; and

26 (B) by inserting “and a notification of the right to
27 appeal such determination and instructions on how to
28 initiate such appeal under this section” after “such de-
29 cision,”.

30 (3) APPEALS.—Section 1869(d) (42 U.S.C.
31 1395ff(d)), as amended by BIPA, is amended—

32 (A) in the heading, by inserting “; NOTICE” after
33 “SECRETARY”; and

34 (B) by adding at the end the following new para-
35 graph:

36 “(4) NOTICE.—Notice of the decision of an adminis-
37 trative law judge shall be in writing in a manner calculated

1 to be understood by the individual entitled to benefits
2 under part A or enrolled under part B, or both, and shall
3 include—

4 “(A) the specific reasons for the determination (in-
5 cluding, to the extent appropriate, a summary of the
6 clinical or scientific evidence used in making the deter-
7 mination);

8 “(B) the procedures for obtaining additional infor-
9 mation concerning the decision; and

10 “(C) notification of the right to appeal the deci-
11 sion and instructions on how to initiate such an appeal
12 under this section.”.

13 (4) SUBMISSION OF RECORD FOR APPEAL.—Section
14 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) by striking
15 “prepare” and inserting “submit” and by striking “with re-
16 spect to” and all that follows through “and relevant poli-
17 cies”.

18 (d) QUALIFIED INDEPENDENT CONTRACTORS.—

19 (1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDE-
20 PENDENT CONTRACTORS.—Section 1869(c)(3) (42 U.S.C.
21 1395ff(c)(3)), as amended by BIPA, is amended—

22 (A) in subparagraph (A), by striking “sufficient
23 training and expertise in medical science and legal mat-
24 ters” and inserting “sufficient medical, legal, and other
25 expertise (including knowledge of the program under
26 this title) and sufficient staffing”; and

27 (B) by adding at the end the following new sub-
28 paragraph:

29 “(K) INDEPENDENCE REQUIREMENTS.—

30 “(i) IN GENERAL.—Subject to clause (ii), a
31 qualified independent contractor shall not conduct
32 any activities in a case unless the entity—

33 “(I) is not a related party (as defined in
34 subsection (g)(5));

35 “(II) does not have a material familial, fi-
36 nancial, or professional relationship with such a
37 party in relation to such case; and

1 “(III) does not otherwise have a conflict of
2 interest with such a party.

3 “(ii) EXCEPTION FOR REASONABLE COM-
4 PENSATION.—Nothing in clause (i) shall be con-
5 strued to prohibit receipt by a qualified inde-
6 pendent contractor of compensation from the Sec-
7 retary for the conduct of activities under this sec-
8 tion if the compensation is provided consistent with
9 clause (iii).

10 “(iii) LIMITATIONS ON ENTITY COMPENSA-
11 TION.—Compensation provided by the Secretary to
12 a qualified independent contractor in connection
13 with reviews under this section shall not be contin-
14 gent on any decision rendered by the contractor or
15 by any reviewing professional.”.

16 (2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—
17 Section 1869 (42 U.S.C. 1395ff), as amended by BIPA, is
18 amended—

19 (A) by amending subsection (c)(3)(D) to read as
20 follows:

21 “(D) QUALIFICATIONS FOR REVIEWERS.—The re-
22 quirements of subsection (g) shall be met (relating to
23 qualifications of reviewing professionals).”; and

24 (B) by adding at the end the following new sub-
25 section:

26 “(g) QUALIFICATIONS OF REVIEWERS.—

27 “(1) IN GENERAL.—In reviewing determinations under
28 this section, a qualified independent contractor shall assure
29 that—

30 “(A) each individual conducting a review shall
31 meet the qualifications of paragraph (2);

32 “(B) compensation provided by the contractor to
33 each such reviewer is consistent with paragraph (3);
34 and

35 “(C) in the case of a review by a panel described
36 in subsection (c)(3)(B) composed of physicians or other
37 health care professionals (each in this subsection re-

ferred to as a ‘reviewing professional’), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), each reviewing professional shall be a physician (allopathic or osteopathic).

“(2) INDEPENDENCE.—

“(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

“(i) not be a related party (as defined in paragraph (5));

“(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

“(iii) not otherwise have a conflict of interest with such a party.

“(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

“(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

“(I) the individual is not involved in the provision of items or services in the case under review;

“(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party objects; and

“(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

1 “(ii) prohibit an individual who has staff privi-
2 leges at the institution where the treatment in-
3 volved takes place from serving as a reviewer mere-
4 ly on the basis of having such staff privileges if the
5 existence of such privileges is disclosed to the Sec-
6 retary and such individual (or authorized represent-
7 ative), and neither party objects; or

8 “(iii) prohibit receipt of compensation by a re-
9 viewing professional from a contractor if the com-
10 pensation is provided consistent with paragraph
11 (3).

12 For purposes of this paragraph, the term ‘participation
13 agreement’ means an agreement relating to the provi-
14 sion of health care services by the individual and does
15 not include the provision of services as a reviewer
16 under this subsection.

17 “(3) LIMITATIONS ON REVIEWER COMPENSATION.—
18 Compensation provided by a qualified independent con-
19 tractor to a reviewer in connection with a review under this
20 section shall not be contingent on the decision rendered by
21 the reviewer.

22 “(4) LICENSURE AND EXPERTISE.—Each reviewing
23 professional shall be—

24 “(A) a physician (allopathic or osteopathic) who is
25 appropriately credentialed or licensed in one or more
26 States to deliver health care services and has medical
27 expertise in the field of practice that is appropriate for
28 the items or services at issue; or

29 “(B) a health care professional who is legally au-
30 thorized in one or more States (in accordance with
31 State law or the State regulatory mechanism provided
32 by State law) to furnish the health care items or serv-
33 ices at issue and has medical expertise in the field of
34 practice that is appropriate for such items or services.

35 “(5) RELATED PARTY DEFINED.—For purposes of this
36 section, the term ‘related party’ means, with respect to a
37 case under this title involving a specific individual entitled

1 to benefits under part A or enrolled under part B, or both,
2 any of the following:

3 “(A) The Secretary, the medicare administrative
4 contractor involved, or any fiduciary, officer, director,
5 or employee of the Department of Health and Human
6 Services, or of such contractor.

7 “(B) The individual (or authorized representative).

8 “(C) The health care professional that provides
9 the items or services involved in the case.

10 “(D) The institution at which the items or services
11 (or treatment) involved in the case are provided.

12 “(E) The manufacturer of any drug or other item
13 that is included in the items or services involved in the
14 case.

15 “(F) Any other party determined under any regu-
16 lations to have a substantial interest in the case in-
17 volved.”.

18 (3) REDUCING MINIMUM NUMBER OF QUALIFIED
19 INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42
20 U.S.C. 1395ff(c)(4)) is amended by striking “not fewer
21 than 12 qualified independent contractors under this sub-
22 section” and inserting “with a sufficient number of quali-
23 fied independent contractors (but not fewer than 4 such
24 contractors) to conduct reconsiderations consistent with the
25 timeframes applicable under this subsection”.

26 (4) EFFECTIVE DATE.—The amendments made by
27 paragraphs (1) and (2) shall be effective as if included in
28 the enactment of the respective provisions of subtitle C of
29 title V of BIPA, (114 Stat. 2763A–534).

30 (5) TRANSITION.—In applying section 1869(g) of the
31 Social Security Act (as added by paragraph (2)), any ref-
32 erence to a medicare administrative contractor shall be
33 deemed to include a reference to a fiscal intermediary
34 under section 1816 of the Social Security Act (42 U.S.C.
35 1395h) and a carrier under section 1842 of such Act (42
36 U.S.C. 1395u).

1 **SEC. 934. PREPAYMENT REVIEW.**

2 (a) IN GENERAL.—Section 1874A, as added by section
3 911(a)(1) and as amended by sections 912(b), 921(b)(1), and
4 921(c)(1), is further amended by adding at the end the fol-
5 lowing new subsection:

6 “(h) CONDUCT OF PREPAYMENT REVIEW.—

7 “(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

8 “(A) IN GENERAL.—A medicare administrative
9 contractor may conduct random prepayment review
10 only to develop a contractor-wide or program-wide
11 claims payment error rates or under such additional
12 circumstances as may be provided under regulations,
13 developed in consultation with providers of services and
14 suppliers.

15 “(B) USE OF STANDARD PROTOCOLS WHEN CON-
16 DUCTING PREPAYMENT REVIEWS.—When a medicare
17 administrative contractor conducts a random prepay-
18 ment review, the contractor may conduct such review
19 only in accordance with a standard protocol for random
20 prepayment audits developed by the Secretary.

21 “(C) CONSTRUCTION.—Nothing in this paragraph
22 shall be construed as preventing the denial of payments
23 for claims actually reviewed under a random prepay-
24 ment review.

25 “(D) RANDOM PREPAYMENT REVIEW.—For pur-
26 poses of this subsection, the term ‘random prepayment
27 review’ means a demand for the production of records
28 or documentation absent cause with respect to a claim.

29 “(2) LIMITATIONS ON NON-RANDOM PREPAYMENT RE-
30 VIEW.—

31 “(A) LIMITATIONS ON INITIATION OF NON-RAN-
32 DOM PREPAYMENT REVIEW.—A medicare administra-
33 tive contractor may not initiate non-random prepay-
34 ment review of a provider of services or supplier based
35 on the initial identification by that provider of services
36 or supplier of an improper billing practice unless there

1 is a likelihood of sustained or high level of payment
2 error (as defined in subsection (i)(3)(A)).

3 “(B) TERMINATION OF NON-RANDOM PREPAY-
4 MENT REVIEW.—The Secretary shall issue regulations
5 relating to the termination, including termination
6 dates, of non-random prepayment review. Such regula-
7 tions may vary such a termination date based upon the
8 differences in the circumstances triggering prepayment
9 review.”.

10 (b) EFFECTIVE DATE.—

11 (1) IN GENERAL.—Except as provided in this sub-
12 section, the amendment made by subsection (a) shall take
13 effect 1 year after the date of the enactment of this Act.

14 (2) DEADLINE FOR PROMULGATION OF CERTAIN REG-
15 ULATIONS.—The Secretary shall first issue regulations
16 under section 1874A(h) of the Social Security Act, as
17 added by subsection (a), by not later than 1 year after the
18 date of the enactment of this Act.

19 (3) APPLICATION OF STANDARD PROTOCOLS FOR RAN-
20 DOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of
21 the Social Security Act, as added by subsection (a), shall
22 apply to random prepayment reviews conducted on or after
23 such date (not later than 1 year after the date of the enact-
24 ment of this Act) as the Secretary shall specify.

25 (c) APPLICATION TO FISCAL INTERMEDIARIES AND CAR-
26 RRIERS.—The provisions of section 1874A(h) of the Social Secu-
27 rity Act, as added by subsection (a), shall apply to each fiscal
28 intermediary under section 1816 of the Social Security Act (42
29 U.S.C. 1395h) and each carrier under section 1842 of such Act
30 (42 U.S.C. 1395u) in the same manner as they apply to medi-
31 care administrative contractors under such provisions.

32 **SEC. 935. RECOVERY OF OVERPAYMENTS.**

33 (a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is
34 amended by adding at the end the following new subsection:

35 “(f) RECOVERY OF OVERPAYMENTS.—

36 “(1) USE OF REPAYMENT PLANS.—

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1 “(A) IN GENERAL.—If the repayment, within 30
2 days by a provider of services or supplier, of an over-
3 payment under this title would constitute a hardship
4 (as defined in subparagraph (B)), subject to subpara-
5 graph (C), upon request of the provider of services or
6 supplier the Secretary shall enter into a plan with the
7 provider of services or supplier for the repayment
8 (through offset or otherwise) of such overpayment over
9 a period of at least 6 months but not longer than 3
10 years (or not longer than 5 years in the case of extreme
11 hardship, as determined by the Secretary). Interest
12 shall accrue on the balance through the period of re-
13 payment. Such plan shall meet terms and conditions
14 determined to be appropriate by the Secretary.

15 “(B) HARDSHIP.—

16 “(i) IN GENERAL.—For purposes of subpara-
17 graph (A), the repayment of an overpayment (or
18 overpayments) within 30 days is deemed to con-
19 stitute a hardship if—

20 “(I) in the case of a provider of services
21 that files cost reports, the aggregate amount of
22 the overpayments exceeds 10 percent of the
23 amount paid under this title to the provider of
24 services for the cost reporting period covered by
25 the most recently submitted cost report; or

26 “(II) in the case of another provider of
27 services or supplier, the aggregate amount of
28 the overpayments exceeds 10 percent of the
29 amount paid under this title to the provider of
30 services or supplier for the previous calendar
31 year.

32 “(ii) RULE OF APPLICATION.—The Secretary
33 shall establish rules for the application of this sub-
34 paragraph in the case of a provider of services or
35 supplier that was not paid under this title during
36 the previous year or was paid under this title only
37 during a portion of that year.

1 “(iii) TREATMENT OF PREVIOUS OVERPAY-
2 MENTS.—If a provider of services or supplier has
3 entered into a repayment plan under subparagraph
4 (A) with respect to a specific overpayment amount,
5 such payment amount under the repayment plan
6 shall not be taken into account under clause (i)
7 with respect to subsequent overpayment amounts.

8 “(C) EXCEPTIONS.—Subparagraph (A) shall not
9 apply if—

10 “(i) the Secretary has reason to suspect that
11 the provider of services or supplier may file for
12 bankruptcy or otherwise cease to do business or
13 discontinue participation in the program under this
14 title; or

15 “(ii) there is an indication of fraud or abuse
16 committed against the program.

17 “(D) IMMEDIATE COLLECTION IF VIOLATION OF
18 REPAYMENT PLAN.—If a provider of services or sup-
19 plier fails to make a payment in accordance with a re-
20 payment plan under this paragraph, the Secretary may
21 immediately seek to offset or otherwise recover the
22 total balance outstanding (including applicable interest)
23 under the repayment plan.

24 “(E) RELATION TO NO FAULT PROVISION.—Noth-
25 ing in this paragraph shall be construed as affecting
26 the application of section 1870(c) (relating to no ad-
27 justment in the cases of certain overpayments).

28 “(2) LIMITATION ON RECOUPMENT.—

29 “(A) IN GENERAL.—In the case of a provider of
30 services or supplier that is determined to have received
31 an overpayment under this title and that seeks a recon-
32 sideration by a qualified independent contractor on
33 such determination under section 1869(b)(1), the Sec-
34 retary may not take any action (or authorize any other
35 person, including any medicare contractor, as defined
36 in subparagraph (C)) to recoup the overpayment until
37 the date the decision on the reconsideration has been

1 rendered. If the provisions of section 1869(b)(1) (pro-
2 viding for such a reconsideration by a qualified inde-
3 pendent contractor) are not in effect, in applying the
4 previous sentence any reference to such a reconsider-
5 ation shall be treated as a reference to a redetermina-
6 tion by the fiscal intermediary or carrier involved.

7 “(B) COLLECTION WITH INTEREST.—Insofar as
8 the determination on such appeal is against the pro-
9 vider of services or supplier, interest on the overpay-
10 ment shall accrue on and after the date of the original
11 notice of overpayment. Insofar as such determination
12 against the provider of services or supplier is later re-
13 versed, the Secretary shall provide for repayment of the
14 amount recouped plus interest at the same rate as
15 would apply under the previous sentence for the period
16 in which the amount was recouped.

17 “(C) MEDICARE CONTRACTOR DEFINED.—For
18 purposes of this subsection, the term ‘medicare con-
19 tractor’ has the meaning given such term in section
20 1889(g).

21 “(3) LIMITATION ON USE OF EXTRAPOLATION.—A
22 medicare contractor may not use extrapolation to determine
23 overpayment amounts to be recovered by recoupment, off-
24 set, or otherwise unless—

25 “(A) there is a sustained or high level of payment
26 error (as defined by the Secretary by regulation); or

27 “(B) documented educational intervention has
28 failed to correct the payment error (as determined by
29 the Secretary).

30 “(4) PROVISION OF SUPPORTING DOCUMENTATION.—
31 In the case of a provider of services or supplier with respect
32 to which amounts were previously overpaid, a medicare con-
33 tractor may request the periodic production of records or
34 supporting documentation for a limited sample of sub-
35 mitted claims to ensure that the previous practice is not
36 continuing.

37 “(5) CONSENT SETTLEMENT REFORMS.—

1 “(A) IN GENERAL.—The Secretary may use a con-
2 sent settlement (as defined in subparagraph (D)) to
3 settle a projected overpayment.

4 “(B) OPPORTUNITY TO SUBMIT ADDITIONAL IN-
5 FORMATION BEFORE CONSENT SETTLEMENT OFFER.—
6 Before offering a provider of services or supplier a con-
7 sent settlement, the Secretary shall—

8 “(i) communicate to the provider of services or
9 supplier—

10 “(I) that, based on a review of the medical
11 records requested by the Secretary, a prelimi-
12 nary evaluation of those records indicates that
13 there would be an overpayment;

14 “(II) the nature of the problems identified
15 in such evaluation; and

16 “(III) the steps that the provider of serv-
17 ices or supplier should take to address the
18 problems; and

19 “(ii) provide for a 45-day period during which
20 the provider of services or supplier may furnish ad-
21 ditional information concerning the medical records
22 for the claims that had been reviewed.

23 “(C) CONSENT SETTLEMENT OFFER.—The Sec-
24 retary shall review any additional information furnished
25 by the provider of services or supplier under subpara-
26 graph (B)(ii). Taking into consideration such informa-
27 tion, the Secretary shall determine if there still appears
28 to be an overpayment. If so, the Secretary—

29 “(i) shall provide notice of such determination
30 to the provider of services or supplier, including an
31 explanation of the reason for such determination;
32 and

33 “(ii) in order to resolve the overpayment, may
34 offer the provider of services or supplier—

35 “(I) the opportunity for a statistically
36 valid random sample; or

37 “(II) a consent settlement.

1 The opportunity provided under clause (ii)(I) does not
2 waive any appeal rights with respect to the alleged
3 overpayment involved.

4 “(D) CONSENT SETTLEMENT DEFINED.—For pur-
5 poses of this paragraph, the term ‘consent settlement’
6 means an agreement between the Secretary and a pro-
7 vider of services or supplier whereby both parties agree
8 to settle a projected overpayment based on less than a
9 statistically valid sample of claims and the provider of
10 services or supplier agrees not to appeal the claims in-
11 volved.

12 “(6) NOTICE OF OVER-UTILIZATION OF CODES.—The
13 Secretary shall establish, in consultation with organizations
14 representing the classes of providers of services and sup-
15 pliers, a process under which the Secretary provides for no-
16 tice to classes of providers of services and suppliers served
17 by the contractor in cases in which the contractor has iden-
18 tified that particular billing codes may be overutilized by
19 that class of providers of services or suppliers under the
20 programs under this title (or provisions of title XI insofar
21 as they relate to such programs).

22 “(7) PAYMENT AUDITS.—

23 “(A) WRITTEN NOTICE FOR POST-PAYMENT AU-
24 DITS.—Subject to subparagraph (C), if a medicare con-
25 tractor decides to conduct a post-payment audit of a
26 provider of services or supplier under this title, the con-
27 tractor shall provide the provider of services or supplier
28 with written notice (which may be in electronic form)
29 of the intent to conduct such an audit.

30 “(B) EXPLANATION OF FINDINGS FOR ALL AU-
31 DITS.—Subject to subparagraph (C), if a medicare con-
32 tractor audits a provider of services or supplier under
33 this title, the contractor shall—

34 “(i) give the provider of services or supplier a
35 full review and explanation of the findings of the
36 audit in a manner that is understandable to the

1 provider of services or supplier and permits the de-
2 velopment of an appropriate corrective action plan;

3 “(ii) inform the provider of services or supplier
4 of the appeal rights under this title as well as con-
5 sent settlement options (which are at the discretion
6 of the Secretary);

7 “(iii) give the provider of services or supplier
8 an opportunity to provide additional information to
9 the contractor; and

10 “(iv) take into account information provided,
11 on a timely basis, by the provider of services or
12 supplier under clause (iii).

13 “(C) EXCEPTION.—Subparagraphs (A) and (B)
14 shall not apply if the provision of notice or findings
15 would compromise pending law enforcement activities,
16 whether civil or criminal, or reveal findings of law en-
17 forcement-related audits.

18 “(8) STANDARD METHODOLOGY FOR PROBE SAM-
19 PLING.—The Secretary shall establish a standard method-
20 ology for medicare contractors to use in selecting a sample
21 of claims for review in the case of an abnormal billing pat-
22 tern.”.

23 (b) EFFECTIVE DATES AND DEADLINES.—

24 (1) USE OF REPAYMENT PLANS.—Section 1893(f)(1)
25 of the Social Security Act, as added by subsection (a), shall
26 apply to requests for repayment plans made after the date
27 of the enactment of this Act.

28 (2) LIMITATION ON RECOUPMENT.—Section
29 1893(f)(2) of the Social Security Act, as added by sub-
30 section (a), shall apply to actions taken after the date of
31 the enactment of this Act.

32 (3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of
33 the Social Security Act, as added by subsection (a), shall
34 apply to statistically valid random samples initiated after
35 the date that is 1 year after the date of the enactment of
36 this Act.

1 (4) PROVISION OF SUPPORTING DOCUMENTATION.—
2 Section 1893(f)(4) of the Social Security Act, as added by
3 subsection (a), shall take effect on the date of the enact-
4 ment of this Act.

5 (5) CONSENT SETTLEMENT.—Section 1893(f)(5) of
6 the Social Security Act, as added by subsection (a), shall
7 apply to consent settlements entered into after the date of
8 the enactment of this Act.

9 (6) NOTICE OF OVERUTILIZATION.—Not later than 1
10 year after the date of the enactment of this Act, the Sec-
11 retary shall first establish the process for notice of over-
12 utilization of billing codes under section 1893A(f)(6) of the
13 Social Security Act, as added by subsection (a).

14 (7) PAYMENT AUDITS.—Section 1893A(f)(7) of the
15 Social Security Act, as added by subsection (a), shall apply
16 to audits initiated after the date of the enactment of this
17 Act.

18 (8) STANDARD FOR ABNORMAL BILLING PATTERNS.—
19 Not later than 1 year after the date of the enactment of
20 this Act, the Secretary shall first establish a standard
21 methodology for selection of sample claims for abnormal
22 billing patterns under section 1893(f)(8) of the Social Se-
23 curity Act, as added by subsection (a).

24 **SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF**
25 **APPEAL.**

26 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is
27 amended—

28 (1) by adding at the end of the heading the following:

29 “; ENROLLMENT PROCESSES”; and

30 (2) by adding at the end the following new subsection:

31 “(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERV-
32 ICES AND SUPPLIERS.—

33 “(1) ENROLLMENT PROCESS.—

34 “(A) IN GENERAL.—The Secretary shall establish
35 by regulation a process for the enrollment of providers
36 of services and suppliers under this title.

1 “(B) DEADLINES.—The Secretary shall establish
2 by regulation procedures under which there are dead-
3 lines for actions on applications for enrollment (and, if
4 applicable, renewal of enrollment). The Secretary shall
5 monitor the performance of medicare administrative
6 contractors in meeting the deadlines established under
7 this subparagraph.

8 “(C) CONSULTATION BEFORE CHANGING PRO-
9 VIDER ENROLLMENT FORMS.—The Secretary shall con-
10 sult with providers of services and suppliers before
11 making changes in the provider enrollment forms re-
12 quired of such providers and suppliers to be eligible to
13 submit claims for which payment may be made under
14 this title.

15 “(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-
16 RENEWAL.—A provider of services or supplier whose appli-
17 cation to enroll (or, if applicable, to renew enrollment)
18 under this title is denied may have a hearing and judicial
19 review of such denial under the procedures that apply
20 under subsection (h)(1)(A) to a provider of services that is
21 dissatisfied with a determination by the Secretary.”.

22 (b) EFFECTIVE DATES.—

23 (1) ENROLLMENT PROCESS.—The Secretary shall pro-
24 vide for the establishment of the enrollment process under
25 section 1866(j)(1) of the Social Security Act, as added by
26 subsection (a)(2), within 6 months after the date of the en-
27 actment of this Act.

28 (2) CONSULTATION.—Section 1866(j)(1)(C) of the So-
29 cial Security Act, as added by subsection (a)(2), shall apply
30 with respect to changes in provider enrollment forms made
31 on or after January 1, 2004.

32 (3) HEARING RIGHTS.—Section 1866(j)(2) of the So-
33 cial Security Act, as added by subsection (a)(2), shall apply
34 to denials occurring on or after such date (not later than
35 1 year after the date of the enactment of this Act) as the
36 Secretary specifies.

SEC. 937. PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS WITHOUT PURSUING APPEALS PROCESS.

(a) CLAIMS.—The Secretary shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(g) of the Social Security Act, as inserted by section 301(a)(1)) and representatives of providers of services and suppliers, a process whereby, in the case of minor errors or omissions (as defined by the Secretary) that are detected in the submission of claims under the programs under title XVIII of such Act, a provider of services or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to resubmit corrected claims.

(b) PERMITTING USE OF CORRECTED AND SUPPLEMENTARY DATA.—

(1) IN GENERAL.—Section 1886(d)(10)(D)(vi) (42 U.S.C. 1395ww(d)(10)(D)(vi)) is amended by adding after subclause (II) at the end the following:

“Notwithstanding subclause (I), a hospital may submit, and the Secretary may accept upon verification, data that corrects or supplements the data described in such subclause without regard to whether the corrected or supplementary data relate to a cost report that has been settled.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to fiscal years beginning with fiscal year 2004.

(3) SUBMITTAL AND RESUBMITTAL OF APPLICATIONS PERMITTED FOR FISCAL YEAR 2004.—

(A) IN GENERAL.—Notwithstanding any other provision of law, a hospital may submit (or resubmit) an application for a change described in section 1886(d)(10)(C)(i)(II) of the Social Security Act for fiscal year 2004 if the hospital demonstrates on a timely basis to the satisfaction of the Secretary that the use of corrected or supplementary data under the amend-

1 ment made by paragraph (1) would materially affect
2 the approval of such an application.

3 (B) APPLICATION OF BUDGET NEUTRALITY.—If
4 one or more hospital's applications are approved as a
5 result of paragraph (1) and subparagraph (A) for fiscal
6 year 2004, the Secretary shall make a proportional ad-
7 justment in the standardized amounts determined
8 under section 1886(d)(3) of the Social Security Act (42
9 U.S.C. 1395ww(d)(3)) for fiscal year 2004 to assure
10 that approval of such applications does not result in
11 aggregate payments under section 1886(d) of such Act
12 that are greater or less than those that would otherwise
13 be made if paragraph (1) and subparagraph (A) did
14 not apply.

15 **SEC. 938. PRIOR DETERMINATION PROCESS FOR CER-**
16 **TAIN ITEMS AND SERVICES; ADVANCE BENE-**
17 **FICIARY NOTICES.**

18 (a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as
19 amended by sections 521 and 522 of BIPA and section
20 933(d)(2)(B), is further amended by adding at the end the fol-
21 lowing new subsection:

22 “(h) PRIOR DETERMINATION PROCESS FOR CERTAIN
23 ITEMS AND SERVICES.—

24 “(1) ESTABLISHMENT OF PROCESS.—

25 “(A) IN GENERAL.—With respect to a medicare
26 administrative contractor that has a contract under
27 section 1874A that provides for making payments
28 under this title with respect to eligible items and serv-
29 ices described in subparagraph (C), the Secretary shall
30 establish a prior determination process that meets the
31 requirements of this subsection and that shall be ap-
32 plied by such contractor in the case of eligible request-
33 ers.

34 “(B) ELIGIBLE REQUESTER.—For purposes of
35 this subsection, each of the following shall be an eligi-
36 ble requester:

1 “(i) A physician, but only with respect to eligi-
2 ble items and services for which the physician may
3 be paid directly.

4 “(ii) An individual entitled to benefits under
5 this title, but only with respect to an item or serv-
6 ice for which the individual receives, from the phy-
7 sician who may be paid directly for the item or
8 service, an advance beneficiary notice under section
9 1879(a) that payment may not be made (or may no
10 longer be made) for the item or service under this
11 title.

12 “(C) ELIGIBLE ITEMS AND SERVICES.—For pur-
13 poses of this subsection and subject to paragraph (2),
14 eligible items and services are items and services which
15 are physicians’ services (as defined in paragraph (4)(A)
16 of section 1848(f) for purposes of calculating the sus-
17 tainable growth rate under such section).

18 “(2) SECRETARIAL FLEXIBILITY.—The Secretary shall
19 establish by regulation reasonable limits on the categories
20 of eligible items and services for which a prior determina-
21 tion of coverage may be requested under this subsection. In
22 establishing such limits, the Secretary may consider the
23 dollar amount involved with respect to the item or service,
24 administrative costs and burdens, and other relevant fac-
25 tors.

26 “(3) REQUEST FOR PRIOR DETERMINATION.—

27 “(A) IN GENERAL.—Subject to paragraph (2),
28 under the process established under this subsection an
29 eligible requester may submit to the contractor a re-
30 quest for a determination, before the furnishing of an
31 eligible item or service involved as to whether the item
32 or service is covered under this title consistent with the
33 applicable requirements of section 1862(a)(1)(A) (relat-
34 ing to medical necessity).

35 “(B) ACCOMPANYING DOCUMENTATION.—The Sec-
36 retary may require that the request be accompanied by
37 a description of the item or service, supporting docu-

1 mentation relating to the medical necessity for the item
2 or service, and any other appropriate documentation.
3 In the case of a request submitted by an eligible re-
4 quester who is described in paragraph (1)(B)(ii), the
5 Secretary may require that the request also be accom-
6 panied by a copy of the advance beneficiary notice in-
7 volved.

8 “(4) RESPONSE TO REQUEST.—

9 “(A) IN GENERAL.—Under such process, the con-
10 tractor shall provide the eligible requester with written
11 notice of a determination as to whether—

12 “(i) the item or service is so covered;

13 “(ii) the item or service is not so covered; or

14 “(iii) the contractor lacks sufficient informa-
15 tion to make a coverage determination.

16 If the contractor makes the determination described in
17 clause (iii), the contractor shall include in the notice a
18 description of the additional information required to
19 make the coverage determination.

20 “(B) DEADLINE TO RESPOND.—Such notice shall
21 be provided within the same time period as the time pe-
22 riod applicable to the contractor providing notice of ini-
23 tial determinations on a claim for benefits under sub-
24 section (a)(2)(A).

25 “(C) INFORMING BENEFICIARY IN CASE OF PHYSI-
26 CIAN REQUEST.—In the case of a request in which an
27 eligible requester is not the individual described in
28 paragraph (1)(B)(ii), the process shall provide that the
29 individual to whom the item or service is proposed to
30 be furnished shall be informed of any determination de-
31 scribed in clause (ii) (relating to a determination of
32 non-coverage) and the right (referred to in paragraph
33 (6)(B)) to obtain the item or service and have a claim
34 submitted for the item or service.

35 “(5) EFFECT OF DETERMINATIONS.—

36 “(A) BINDING NATURE OF POSITIVE DETERMINA-
37 TION.—If the contractor makes the determination de-

scribed in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

“(B) NOTICE AND RIGHT TO REDETERMINATION IN CASE OF A DENIAL.—

“(i) IN GENERAL.—If the contractor makes the determination described in paragraph (4)(A)(ii)—

“(I) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered; and

“(II) the contractor shall include in notice under paragraph (4)(A) a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and the right to such a redetermination.

“(ii) DEADLINE FOR REDETERMINATIONS.—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor providing notice of redeterminations relating to a claim for benefits under subsection (a)(3)(C)(ii).

“(6) LIMITATION ON FURTHER REVIEW.—

“(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims are not subject to further administrative appeal or judicial review under this section or otherwise.

“(B) DECISION NOT TO SEEK PRIOR DETERMINATION OR NEGATIVE DETERMINATION DOES NOT IMPACT RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT, OR APPEAL RIGHTS.—Nothing in this subsection shall

1 be construed as affecting the right of an individual
2 who—

3 “(i) decides not to seek a prior determination
4 under this subsection with respect to items or serv-
5 ices; or

6 “(ii) seeks such a determination and has re-
7 ceived a determination described in paragraph
8 (4)(A)(ii),

9 from receiving (and submitting a claim for) such items
10 services and from obtaining administrative or judicial
11 review respecting such claim under the other applicable
12 provisions of this section. Failure to seek a prior deter-
13 mination under this subsection with respect to items
14 and services shall not be taken into account in such ad-
15 ministrative or judicial review.

16 “(C) NO PRIOR DETERMINATION AFTER RECEIPT
17 OF SERVICES.—Once an individual is provided items
18 and services, there shall be no prior determination
19 under this subsection with respect to such items or
20 services.”.

21 (b) EFFECTIVE DATE; TRANSITION.—

22 (1) EFFECTIVE DATE.—The Secretary shall establish
23 the prior determination process under the amendment
24 made by subsection (a) in such a manner as to provide for
25 the acceptance of requests for determinations under such
26 process filed not later than 18 months after the date of the
27 enactment of this Act.

28 (2) TRANSITION.—During the period in which the
29 amendment made by subsection (a) has become effective
30 but contracts are not provided under section 1874A of the
31 Social Security Act with medicare administrative contrac-
32 tors, any reference in section 1869(g) of such Act (as
33 added by such amendment) to such a contractor is deemed
34 a reference to a fiscal intermediary or carrier with an
35 agreement under section 1816, or contract under section
36 1842, respectively, of such Act.

1 (3) LIMITATION ON APPLICATION TO SGR.—For pur-
2 poses of applying section 1848(f)(2)(D) of the Social Secu-
3 rity Act (42 U.S.C. 1395w-4(f)(2)(D)), the amendment
4 made by subsection (a) shall not be considered to be a
5 change in law or regulation.

6 (c) PROVISIONS RELATING TO ADVANCE BENEFICIARY
7 NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

8 (1) DATA COLLECTION.—The Secretary shall establish
9 a process for the collection of information on the instances
10 in which an advance beneficiary notice (as defined in para-
11 graph (5)) has been provided and on instances in which a
12 beneficiary indicates on such a notice that the beneficiary
13 does not intend to seek to have the item or service that is
14 the subject of the notice furnished.

15 (2) OUTREACH AND EDUCATION.—The Secretary shall
16 establish a program of outreach and education for bene-
17 ficiaries and providers of services and other persons on the
18 appropriate use of advance beneficiary notices and coverage
19 policies under the medicare program.

20 (3) GAO REPORT REPORT ON USE OF ADVANCE BENE-
21 FICIARY NOTICES.—Not later than 18 months after the
22 date on which section 1869(g) of the Social Security Act
23 (as added by subsection (a)) takes effect, the Comptroller
24 General of the United States shall submit to Congress a re-
25 port on the use of advance beneficiary notices under title
26 XVIII of such Act. Such report shall include information
27 concerning the providers of services and other persons that
28 have provided such notices and the response of beneficiaries
29 to such notices.

30 (4) GAO REPORT ON USE OF PRIOR DETERMINATION
31 PROCESS.—Not later than 18 months after the date on
32 which section 1869(g) of the Social Security Act (as added
33 by subsection (a)) takes effect, the Comptroller General of
34 the United States shall submit to Congress a report on the
35 use of the prior determination process under such section.
36 Such report shall include—

1 (A) information concerning the types of proce-
2 dures for which a prior determination has been sought,
3 determinations made under the process, and changes in
4 receipt of services resulting from the application of
5 such process; and

6 (B) an evaluation of whether the process was use-
7 ful for physicians (and other suppliers) and bene-
8 ficiaries, whether it was timely, and whether the
9 amount of information required was burdensome to
10 physicians and beneficiaries.

11 (5) ADVANCE BENEFICIARY NOTICE DEFINED.—In
12 this subsection, the term “advance beneficiary notice”
13 means a written notice provided under section 1879(a) of
14 the Social Security Act (42 U.S.C. 1395pp(a)) to an indi-
15 vidual entitled to benefits under part A or B of title XVIII
16 of such Act before items or services are furnished under
17 such part in cases where a provider of services or other
18 person that would furnish the item or service believes that
19 payment will not be made for some or all of such items or
20 services under such title.

21 **Subtitle V—Miscellaneous Provisions**

22 **SEC. 941. POLICY DEVELOPMENT REGARDING EVALUA-** 23 **TION AND MANAGEMENT (E & M) DOCU-** 24 **MENTATION GUIDELINES.**

25 (a) IN GENERAL.—The Secretary may not implement any
26 new documentation guidelines for, or clinical examples of, eval-
27 uation and management physician services under the title
28 XVIII of the Social Security Act on or after the date of the
29 enactment of this Act unless the Secretary—

30 (1) has developed the guidelines in collaboration with
31 practicing physicians (including both generalists and spe-
32 cialists) and provided for an assessment of the proposed
33 guidelines by the physician community;

34 (2) has established a plan that contains specific goals,
35 including a schedule, for improving the use of such guide-
36 lines;

(3) has conducted appropriate and representative pilot projects under subsection (b) to test modifications to the evaluation and management documentation guidelines;

(4) finds that the objectives described in subsection (c) will be met in the implementation of such guidelines; and

(5) has established, and is implementing, a program to educate physicians on the use of such guidelines and that includes appropriate outreach.

The Secretary shall make changes to the manner in which existing evaluation and management documentation guidelines are implemented to reduce paperwork burdens on physicians.

(b) PILOT PROJECTS TO TEST EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES.—

(1) IN GENERAL.—The Secretary shall conduct under this subsection appropriate and representative pilot projects to test new evaluation and management documentation guidelines referred to in subsection (a).

(2) LENGTH AND CONSULTATION.—Each pilot project under this subsection shall—

(A) be voluntary;

(B) be of sufficient length as determined by the Secretary to allow for preparatory physician and medicare contractor education, analysis, and use and assessment of potential evaluation and management guidelines; and

(C) be conducted, in development and throughout the planning and operational stages of the project, in consultation with practicing physicians (including both generalists and specialists).

(3) RANGE OF PILOT PROJECTS.—Of the pilot projects conducted under this subsection—

(A) at least one shall focus on a peer review method by physicians (not employed by a medicare contractor) which evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to definitions published in the Current

1 Procedures Terminology (CPT) code book of the Amer-
2 ican Medical Association;

3 (B) at least one shall focus on an alternative
4 method to detailed guidelines based on physician docu-
5 mentation of face to face encounter time with a patient;

6 (C) at least one shall be conducted for services
7 furnished in a rural area and at least one for services
8 furnished outside such an area; and

9 (D) at least one shall be conducted in a setting
10 where physicians bill under physicians' services in
11 teaching settings and at least one shall be conducted in
12 a setting other than a teaching setting.

13 (4) BANNING OF TARGETING OF PILOT PROJECT PAR-
14 TICIPANTS.—Data collected under this subsection shall not
15 be used as the basis for overpayment demands or post-pay-
16 ment audits. Such limitation applies only to claims filed as
17 part of the pilot project and lasts only for the duration of
18 the pilot project and only as long as the provider is a par-
19 ticipant in the pilot project.

20 (5) STUDY OF IMPACT.—Each pilot project shall ex-
21 amine the effect of the new evaluation and management
22 documentation guidelines on—

23 (A) different types of physician practices, includ-
24 ing those with fewer than 10 full-time-equivalent em-
25 ployees (including physicians); and

26 (B) the costs of physician compliance, including
27 education, implementation, auditing, and monitoring.

28 (6) PERIODIC REPORTS.—The Secretary shall submit
29 to Congress periodic reports on the pilot projects under this
30 subsection.

31 (c) OBJECTIVES FOR EVALUATION AND MANAGEMENT
32 GUIDELINES.—The objectives for modified evaluation and man-
33 agement documentation guidelines developed by the Secretary
34 shall be to—

35 (1) identify clinically relevant documentation needed to
36 code accurately and assess coding levels accurately;

1 (2) decrease the level of non-clinically pertinent and
2 burdensome documentation time and content in the physi-
3 cian's medical record;

4 (3) increase accuracy by reviewers; and

5 (4) educate both physicians and reviewers.

6 (d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOC-
7 UMENTATION FOR PHYSICIAN CLAIMS.—

8 (1) STUDY.—The Secretary shall carry out a study of
9 the matters described in paragraph (2).

10 (2) MATTERS DESCRIBED.—The matters referred to in
11 paragraph (1) are—

12 (A) the development of a simpler, alternative sys-
13 tem of requirements for documentation accompanying
14 claims for evaluation and management physician serv-
15 ices for which payment is made under title XVIII of
16 the Social Security Act; and

17 (B) consideration of systems other than current
18 coding and documentation requirements for payment
19 for such physician services.

20 (3) CONSULTATION WITH PRACTICING PHYSICIANS.—
21 In designing and carrying out the study under paragraph
22 (1), the Secretary shall consult with practicing physicians,
23 including physicians who are part of group practices and
24 including both generalists and specialists.

25 (4) APPLICATION OF HIPAA UNIFORM CODING RE-
26 QUIREMENTS.—In developing an alternative system under
27 paragraph (2), the Secretary shall consider requirements of
28 administrative simplification under part C of title XI of the
29 Social Security Act.

30 (5) REPORT TO CONGRESS.—(A) Not later than Octo-
31 ber 1, 2005, the Secretary shall submit to Congress a re-
32 port on the results of the study conducted under paragraph
33 (1).

34 (B) The Medicare Payment Advisory Commission shall
35 conduct an analysis of the results of the study included in
36 the report under subparagraph (A) and shall submit a re-
37 port on such analysis to Congress.

(e) STUDY ON APPROPRIATE CODING OF CERTAIN EXTENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. Not later than October 1, 2005, the Secretary shall submit a report to Congress on such study and shall include recommendations on how to code appropriately for such visits in a manner that takes into account the amount of time the physician spent with the patient.

(f) DEFINITIONS.—In this section—

(1) the term “rural area” has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act, 42 U.S.C. 1395ww(d)(2)(D); and

(2) the term “teaching settings” are those settings described in section 415.150 of title 42, Code of Federal Regulations.

SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECHNOLOGY AND COVERAGE.

(a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Section 1868 (42 U.S.C. 1395ee), as amended by section 921(a), is amended by adding at the end the following new subsection:

“(c) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

“(1) ESTABLISHMENT.—The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as ‘CMS’).

“(2) COMPOSITION.—The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

“(3) DUTIES.—The Council shall coordinate the activities of coverage, coding, and payment processes under this title with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

“(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.—The Secretary shall appoint (or des-

1 igrate) a noncareer appointee (as defined in section
2 3132(a)(7) of title 5, United States Code) who shall serve
3 as the Executive Coordinator for Technology and Innova-
4 tion. Such executive coordinator shall report to the Admin-
5 istrator of CMS, shall chair the Council, shall oversee the
6 execution of its duties, and shall serve as a single point of
7 contact for outside groups and entities regarding the cov-
8 erage, coding, and payment processes under this title.”.

9 (b) METHODS FOR DETERMINING PAYMENT BASIS FOR
10 NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 1395l(h)) is
11 amended by adding at the end the following:

12 “(8)(A) The Secretary shall establish by regulation proce-
13 dures for determining the basis for, and amount of, payment
14 under this subsection for any clinical diagnostic laboratory test
15 with respect to which a new or substantially revised HCPCS
16 code is assigned on or after January 1, 2005 (in this para-
17 graph referred to as ‘new tests’).

18 “(B) Determinations under subparagraph (A) shall be
19 made only after the Secretary—

20 “(i) makes available to the public (through an Internet
21 site and other appropriate mechanisms) a list that includes
22 any such test for which establishment of a payment amount
23 under this subsection is being considered for a year;

24 “(ii) on the same day such list is made available,
25 causes to have published in the Federal Register notice of
26 a meeting to receive comments and recommendations (and
27 data on which recommendations are based) from the public
28 on the appropriate basis under this subsection for estab-
29 lishing payment amounts for the tests on such list;

30 “(iii) not less than 30 days after publication of such
31 notice convenes a meeting, that includes representatives of
32 officials of the Centers for Medicare & Medicaid Services
33 involved in determining payment amounts, to receive such
34 comments and recommendations (and data on which the
35 recommendations are based);

36 “(iv) taking into account the comments and rec-
37 ommendations (and accompanying data) received at such

1 meeting, develops and makes available to the public
2 (through an Internet site and other appropriate mecha-
3 nisms) a list of proposed determinations with respect to the
4 appropriate basis for establishing a payment amount under
5 this subsection for each such code, together with an expla-
6 nation of the reasons for each such determination, the data
7 on which the determinations are based, and a request for
8 public written comments on the proposed determination;
9 and

10 “(v) taking into account the comments received during
11 the public comment period, develops and makes available to
12 the public (through an Internet site and other appropriate
13 mechanisms) a list of final determinations of the payment
14 amounts for such tests under this subsection, together with
15 the rationale for each such determination, the data on
16 which the determinations are based, and responses to com-
17 ments and suggestions received from the public.

18 “(C) Under the procedures established pursuant to sub-
19 paragraph (A), the Secretary shall—

20 “(i) set forth the criteria for making determinations
21 under subparagraph (A); and

22 “(ii) make available to the public the data (other than
23 proprietary data) considered in making such determina-
24 tions.

25 “(D) The Secretary may convene such further public meet-
26 ings to receive public comments on payment amounts for new
27 tests under this subsection as the Secretary deems appropriate.

28 “(E) For purposes of this paragraph:

29 “(i) The term ‘HCPSC’ refers to the Health Care Pro-
30 cedure Coding System.

31 “(ii) A code shall be considered to be ‘substantially re-
32 vised’ if there is a substantive change to the definition of
33 the test or procedure to which the code applies (such as a
34 new analyte or a new methodology for measuring an exist-
35 ing analyte-specific test).”.

1 (c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA
2 COLLECTION FOR USE IN THE MEDICARE INPATIENT PAY-
3 MENT SYSTEM.—

4 (1) STUDY.—The Comptroller General of the United
5 States shall conduct a study that analyzes which external
6 data can be collected in a shorter time frame by the Cen-
7 ters for Medicare & Medicaid Services for use in computing
8 payments for inpatient hospital services. The study may in-
9 clude an evaluation of the feasibility and appropriateness of
10 using of quarterly samples or special surveys or any other
11 methods. The study shall include an analysis of whether
12 other executive agencies, such as the Bureau of Labor Sta-
13 tistics in the Department of Commerce, are best suited to
14 collect this information.

15 (2) REPORT.—By not later than October 1, 2004, the
16 Comptroller General shall submit a report to Congress on
17 the study under paragraph (1).

18 (d) PROCESS FOR ADOPTION OF ICD CODES AS DATA
19 STANDARD.—Section 1172(f) (42 U.S.C. 1320d-1(f)) is
20 amended by inserting after the first sentence the following:
21 “Notwithstanding the preceding sentence, if the National Com-
22 mittee on Vital and Health Statistics has not made a rec-
23 ommendation to the Secretary before the date of the enactment
24 of this sentence, with respect to the adoption of the Inter-
25 national Classification of Diseases, 10th Revision, Procedure
26 Coding System (‘ICD-10-PCS’) and the International Classi-
27 fication of Diseases, 10th Revision, Clinical Modification
28 (‘ICD-10-CM’) as a standard under this part for the reporting
29 of diagnoses, the Secretary may implement ICD-10-PCS only
30 with respect to inpatient services as such a standard.”.

31 **SEC. 943. TREATMENT OF HOSPITALS FOR CERTAIN**
32 **SERVICES UNDER MEDICARE SECONDARY**
33 **PAYOR (MSP) PROVISIONS.**

34 (a) IN GENERAL.—The Secretary shall not require a hos-
35 pital (including a critical access hospital) to ask questions (or
36 obtain information) relating to the application of section
37 1862(b) of the Social Security Act (relating to medicare sec-

1 ondary payor provisions) in the case of reference laboratory
2 services described in subsection (b), if the Secretary does not
3 impose such requirement in the case of such services furnished
4 by an independent laboratory.

5 (b) REFERENCE LABORATORY SERVICES DESCRIBED.—
6 Reference laboratory services described in this subsection are
7 clinical laboratory diagnostic tests (or the interpretation of
8 such tests, or both) furnished without a face-to-face encounter
9 between the individual entitled to benefits under part A or en-
10 rolled under part B, or both, and the hospital involved and in
11 which the hospital submits a claim only for such test or inter-
12 pretation.

13 **SEC. 944. EMTALA IMPROVEMENTS.**

14 (a) PAYMENT FOR EMTALA-MANDATED SCREENING AND
15 STABILIZATION SERVICES.—

16 (1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is
17 amended by inserting after subsection (c) the following new
18 subsection:

19 “(d) For purposes of subsection (a)(1)(A), in the case of
20 any item or service that is required to be provided pursuant to
21 section 1867 to an individual who is entitled to benefits under
22 this title, determinations as to whether the item or service is
23 reasonable and necessary shall be made on the basis of the in-
24 formation available to the treating physician or practitioner (in-
25 cluding the patient’s presenting symptoms or complaint) at the
26 time the item or service was ordered or furnished by the physi-
27 cian or practitioner (and not on the patient’s principal diag-
28 nosis). When making such determinations with respect to such
29 an item or service, the Secretary shall not consider the fre-
30 quency with which the item or service was provided to the pa-
31 tient before or after the time of the admission or visit.”.

32 (2) EFFECTIVE DATE.—The amendment made by
33 paragraph (1) shall apply to items and services furnished
34 on or after January 1, 2004.

35 (b) NOTIFICATION OF PROVIDERS WHEN EMTALA IN-
36 VESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42 U.S.C.

1 1395dd(d)) is amended by adding at the end the following new
2 paragraph:

3 “(4) NOTICE UPON CLOSING AN INVESTIGATION.—The
4 Secretary shall establish a procedure to notify hospitals and
5 physicians when an investigation under this section is
6 closed.”.

7 (c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN
8 EMTALA CASES INVOLVING TERMINATION OF PARTICIPA-
9 TION.—

10 (1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C.
11 1395dd(d)(3)) is amended—

12 (A) in the first sentence, by inserting “or in termi-
13 nating a hospital’s participation under this title” after
14 “in imposing sanctions under paragraph (1)”; and

15 (B) by adding at the end the following new sen-
16 tences: “Except in the case in which a delay would
17 jeopardize the health or safety of individuals, the Sec-
18 retary shall also request such a review before making
19 a compliance determination as part of the process of
20 terminating a hospital’s participation under this title
21 for violations related to the appropriateness of a med-
22 ical screening examination, stabilizing treatment, or an
23 appropriate transfer as required by this section, and
24 shall provide a period of 5 days for such review. The
25 Secretary shall provide a copy of the organization’s re-
26 port to the hospital or physician consistent with con-
27 fidentiality requirements imposed on the organization
28 under such part B.”.

29 (2) EFFECTIVE DATE.—The amendments made by
30 paragraph (1) shall apply to terminations of participation
31 initiated on or after the date of the enactment of this Act.

32 **SEC. 945. EMERGENCY MEDICAL TREATMENT AND AC-**
33 **TIVE LABOR ACT (EMTALA) TECHNICAL AD-**
34 **VISORY GROUP.**

35 (a) ESTABLISHMENT.—The Secretary shall establish a
36 Technical Advisory Group (in this section referred to as the
37 “Advisory Group”) to review issues related to the Emergency

1 Medical Treatment and Labor Act (EMTALA) and its imple-
2 mentation. In this section, the term “EMTALA” refers to the
3 provisions of section 1867 of the Social Security Act (42 U.S.C.
4 1395dd).

5 (b) MEMBERSHIP.—The Advisory Group shall be com-
6 posed of 19 members, including the Administrator of the Cen-
7 ters for Medicare & Medicaid Services and the Inspector Gen-
8 eral of the Department of Health and Human Services and of
9 which—

10 (1) 4 shall be representatives of hospitals, including at
11 least one public hospital, that have experience with the ap-
12 plication of EMTALA and at least 2 of which have not
13 been cited for EMTALA violations;

14 (2) 7 shall be practicing physicians drawn from the
15 fields of emergency medicine, cardiology or cardiothoracic
16 surgery, orthopedic surgery, neurosurgery, pediatrics or a
17 pediatric subspecialty, obstetrics-gynecology, and psychi-
18 atry, with not more than one physician from any particular
19 field;

20 (3) 2 shall represent patients;

21 (4) 2 shall be staff involved in EMTALA investiga-
22 tions from different regional offices of the Centers for
23 Medicare & Medicaid Services; and

24 (5) 1 shall be from a State survey office involved in
25 EMTALA investigations and 1 shall be from a peer review
26 organization, both of whom shall be from areas other than
27 the regions represented under paragraph (4).

28 In selecting members described in paragraphs (1) through (3),
29 the Secretary shall consider qualified individuals nominated by
30 organizations representing providers and patients.

31 (c) GENERAL RESPONSIBILITIES.—The Advisory Group—

32 (1) shall review EMTALA regulations;

33 (2) may provide advice and recommendations to the
34 Secretary with respect to those regulations and their appli-
35 cation to hospitals and physicians;

1 (3) shall solicit comments and recommendations from
2 hospitals, physicians, and the public regarding the imple-
3 mentation of such regulations; and

4 (4) may disseminate information on the application of
5 such regulations to hospitals, physicians, and the public.

6 (d) ADMINISTRATIVE MATTERS.—

7 (1) CHAIRPERSON.—The members of the Advisory
8 Group shall elect a member to serve as chairperson of the
9 Advisory Group for the life of the Advisory Group.

10 (2) MEETINGS.—The Advisory Group shall first meet
11 at the direction of the Secretary. The Advisory Group shall
12 then meet twice per year and at such other times as the
13 Advisory Group may provide.

14 (e) TERMINATION.—The Advisory Group shall terminate
15 30 months after the date of its first meeting.

16 (f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Sec-
17 retary shall establish the Advisory Group notwithstanding any
18 limitation that may apply to the number of advisory committees
19 that may be established (within the Department of Health and
20 Human Services or otherwise).

21 **SEC. 946. AUTHORIZING USE OF ARRANGEMENTS TO**
22 **PROVIDE CORE HOSPICE SERVICES IN CER-**
23 **TAIN CIRCUMSTANCES.**

24 (a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C.
25 1395x(dd)(5)) is amended by adding at the end the following:

26 “(D) In extraordinary, exigent, or other non-routine cir-
27 cumstances, such as unanticipated periods of high patient
28 loads, staffing shortages due to illness or other events, or tem-
29 porary travel of a patient outside a hospice program’s service
30 area, a hospice program may enter into arrangements with an-
31 other hospice program for the provision by that other program
32 of services described in paragraph (2)(A)(ii)(I). The provisions
33 of paragraph (2)(A)(ii)(II) shall apply with respect to the serv-
34 ices provided under such arrangements.

35 “(E) A hospice program may provide services described in
36 paragraph (1)(A) other than directly by the program if the
37 services are highly specialized services of a registered profes-

1 sional nurse and are provided non-routinely and so infrequently
2 so that the provision of such services directly would be imprac-
3 ticable and prohibitively expensive.”.

4 (b) CONFORMING PAYMENT PROVISION.—Section 1814(i)
5 (42 U.S.C. 1395f(i)) is amended by adding at the end the fol-
6 lowing new paragraph:

7 “(4) In the case of hospice care provided by a hospice pro-
8 gram under arrangements under section 1861(dd)(5)(D) made
9 by another hospice program, the hospice program that made
10 the arrangements shall bill and be paid for the hospice care.”.

11 (c) EFFECTIVE DATE.—The amendments made by this
12 section shall apply to hospice care provided on or after the date
13 of the enactment of this Act.

14 **SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHO-**
15 **GENS STANDARD TO CERTAIN HOSPITALS.**

16 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is
17 amended—

18 (1) in subsection (a)(1)—

19 (A) in subparagraph (R), by striking “and” at the
20 end;

21 (B) in subparagraph (S), by striking the period at
22 the end and inserting “, and”; and

23 (C) by inserting after subparagraph (S) the fol-
24 lowing new subparagraph:

25 “(T) in the case of hospitals that are not otherwise
26 subject to the Occupational Safety and Health Act of 1970,
27 to comply with the Bloodborne Pathogens standard under
28 section 1910.1030 of title 29 of the Code of Federal Regu-
29 lations (or as subsequently redesignated).”; and

30 (2) by adding at the end of subsection (b) the fol-
31 lowing new paragraph:

32 “(4)(A) A hospital that fails to comply with the require-
33 ment of subsection (a)(1)(T) (relating to the Bloodborne
34 Pathogens standard) is subject to a civil money penalty in an
35 amount described in subparagraph (B), but is not subject to
36 termination of an agreement under this section.

1 “(B) The amount referred to in subparagraph (A) is an
2 amount that is similar to the amount of civil penalties that may
3 be imposed under section 17 of the Occupational Safety and
4 Health Act of 1970 for a violation of the Bloodborne Pathogens
5 standard referred to in subsection (a)(1)(T) by a hospital that
6 is subject to the provisions of such Act.

7 “(C) A civil money penalty under this paragraph shall be
8 imposed and collected in the same manner as civil money pen-
9 alties under subsection (a) of section 1128A are imposed and
10 collected under that section.”.

11 (b) EFFECTIVE DATE.—The amendments made by this
12 subsection (a) shall apply to hospitals as of July 1, 2004.

13 **SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS AND**
14 **CORRECTIONS.**

15 (a) TECHNICAL AMENDMENTS RELATING TO ADVISORY
16 COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of
17 section 1114 (42 U.S.C. 1314)—

18 (A) is transferred to section 1862 and added at the
19 end of such section; and

20 (B) is redesignated as subsection (j).

21 (2) Section 1862 (42 U.S.C. 1395y) is amended—

22 (A) in the last sentence of subsection (a), by striking
23 “established under section 1114(f)”; and

24 (B) in subsection (j), as so transferred and
25 redesignated—

26 (i) by striking “under subsection (f)”; and

27 (ii) by striking “section 1862(a)(1)” and inserting
28 “subsection (a)(1)”.

29 (b) TERMINOLOGY CORRECTIONS.—(1) Section
30 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)), as amended by
31 section 521 of BIPA, is amended—

32 (A) in subclause (III), by striking “policy” and insert-
33 ing “determination”; and

34 (B) in subclause (IV), by striking “medical review
35 policies” and inserting “coverage determinations”.

36 (2) Section 1852(a)(2)(C) (42 U.S.C. 1395w-22(a)(2)(C))
37 is amended by striking “policy” and “POLICY” and inserting

1 “determination” each place it appears and “DETERMINATION”,
2 respectively.

3 (c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42
4 U.S.C. 1395ff(f)(4)), as added by section 522 of BIPA, is
5 amended—

6 (1) in subparagraph (A)(iv), by striking “subclause
7 (I), (II), or (III)” and inserting “clause (i), (ii), or (iii)”;

8 (2) in subparagraph (B), by striking “clause (i)(IV)”
9 and “clause (i)(III)” and inserting “subparagraph (A)(iv)”
10 and “subparagraph (A)(iii)”, respectively; and

11 (3) in subparagraph (C), by striking “clause (i)”,
12 “subclause (IV)” and “subparagraph (A)” and inserting
13 “subparagraph (A)”, “clause (iv)” and “paragraph
14 (1)(A)”, respectively each place it appears.

15 (d) OTHER CORRECTIONS.—Effective as if included in the
16 enactment of section 521(c) of BIPA, section 1154(e) (42
17 U.S.C. 1320c–3(e)) is amended by striking paragraph (5).

18 (e) EFFECTIVE DATE.—Except as otherwise provided, the
19 amendments made by this section shall be effective as if in-
20 cluded in the enactment of BIPA.

21 **SEC. 949. CONFORMING AUTHORITY TO WAIVE A PRO-**
22 **GRAM EXCLUSION.**

23 The first sentence of section 1128(c)(3)(B) (42 U.S.C.
24 1320a–7(c)(3)(B)) is amended to read as follows: “Subject to
25 subparagraph (G), in the case of an exclusion under subsection
26 (a), the minimum period of exclusion shall be not less than five
27 years, except that, upon the request of the administrator of a
28 Federal health care program (as defined in section 1128B(f))
29 who determines that the exclusion would impose a hardship on
30 individuals entitled to benefits under part A of title XVIII or
31 enrolled under part B of such title, or both, the Secretary may
32 waive the exclusion under subsection (a)(1), (a)(3), or (a)(4)
33 with respect to that program in the case of an individual or en-
34 tity that is the sole community physician or sole source of es-
35 sential specialized services in a community.”.

1 **SEC. 950. TREATMENT OF CERTAIN DENTAL CLAIMS.**

2 (a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is
3 amended by adding after subsection (g) the following new sub-
4 section:

5 “(h)(1) Subject to paragraph (2), a group health plan (as
6 defined in subsection (a)(1)(A)(v)) providing supplemental or
7 secondary coverage to individuals also entitled to services under
8 this title shall not require a medicare claims determination
9 under this title for dental benefits specifically excluded under
10 subsection (a)(12) as a condition of making a claims deter-
11 mination for such benefits under the group health plan.

12 “(2) A group health plan may require a claims determina-
13 tion under this title in cases involving or appearing to involve
14 inpatient dental hospital services or dental services expressly
15 covered under this title pursuant to actions taken by the Sec-
16 retary.”.

17 (b) EFFECTIVE DATE.—The amendment made by sub-
18 section (a) shall take effect on the date that is 60 days after
19 the date of the enactment of this Act.

20 **SEC. 951. FURNISHING HOSPITALS WITH INFORMATION**
21 **TO COMPUTE DSH FORMULA.**

22 Beginning not later than 1 year after the date of the en-
23 actment of this Act, the Secretary shall furnish to subsection
24 (d) hospitals (as defined in section 1886(d)(1)(B) of the Social
25 Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data necessary
26 for such hospitals to compute the number of patient days de-
27 scribed in subclause (II) of section 1886(d)(5)(F)(vi) of the So-
28 cial Security Act (42 U.S.C. 1395ww(d)(5)(F)(vi)) used in
29 computing the disproportionate patient percentage under such
30 section for that hospital. Such data shall also be furnished to
31 other hospitals which would qualify for additional payments
32 under part A of title XVIII of the Social Security Act on the
33 basis of such data.

34 **SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.**

35 (a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C.
36 1395u(b)(6)(A)) is amended by striking “or (ii) (where the
37 service was provided in a hospital, critical access hospital, clin-

1 ic, or other facility) to the facility in which the service was pro-
2 vided if there is a contractual arrangement between such physi-
3 cian or other person and such facility under which such facility
4 submits the bill for such service,” and inserting “or (ii) where
5 the service was provided under a contractual arrangement be-
6 tween such physician or other person and an entity (as defined
7 by the Secretary), to the entity if, under the contractual ar-
8 rangement, the entity submits the bill for the service and the
9 contractual arrangement meets such other program integrity
10 and other safeguards as the Secretary may determine to be ap-
11 propriate,”.

12 (b) CONFORMING AMENDMENT.—The second sentence of
13 section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is amended by
14 striking “except to an employer or facility” and inserting “ex-
15 cept to an employer, entity, or other person”.

16 (c) EFFECTIVE DATE.—The amendments made by section
17 shall apply to payments made on or after the date of the enact-
18 ment of this Act.

19 **SEC. 953. OTHER PROVISIONS.**

20 (a) GAO REPORTS ON THE PHYSICIAN COMPENSATION.—

21 (1) SUSTAINABLE GROWTH RATE AND UPDATES.—
22 Not later than 6 months after the date of the enactment
23 of this Act, the Comptroller General of the United States
24 shall submit to Congress a report on the appropriateness
25 of the updates in the conversion factor under subsection
26 (d)(3) of section 1848 of the Social Security Act (42
27 U.S.C. 1395w-4), including the appropriateness of the sus-
28 tainable growth rate formula under subsection (f) of such
29 section for 2002 and succeeding years. Such report shall
30 examine the stability and predictability of such updates and
31 rate and alternatives for the use of such rate in the up-
32 dates.

33 (2) PHYSICIAN COMPENSATION GENERALLY.—Not
34 later than 12 months after the date of the enactment of
35 this Act, the Comptroller General shall submit to Congress
36 a report on all aspects of physician compensation for serv-
37 ices furnished under title XVIII of the Social Security Act,

1 and how those aspects interact and the effect on appro-
2 priate compensation for physician services. Such report
3 shall review alternatives for the physician fee schedule
4 under section 1848 of such title (42 U.S.C. 1395w-4).

5 (b) ANNUAL PUBLICATION OF LIST OF NATIONAL COV-
6 ERAGE DETERMINATIONS.—The Secretary shall provide, in an
7 appropriate annual publication available to the public, a list of
8 national coverage determinations made under title XVIII of the
9 Social Security Act in the previous year and information on
10 how to get more information with respect to such determina-
11 tions.

12 (c) GAO REPORT ON FLEXIBILITY IN APPLYING HOME
13 HEALTH CONDITIONS OF PARTICIPATION TO PATIENTS WHO
14 ARE NOT MEDICARE BENEFICIARIES.—Not later than 6
15 months after the date of the enactment of this Act, the Comp-
16 troller General of the United States shall submit to Congress
17 a report on the implications if there were flexibility in the ap-
18 plication of the medicare conditions of participation for home
19 health agencies with respect to groups or types of patients who
20 are not medicare beneficiaries. The report shall include an
21 analysis of the potential impact of such flexible application on
22 clinical operations and the recipients of such services and an
23 analysis of methods for monitoring the quality of care provided
24 to such recipients.

25 (d) OIG REPORT ON NOTICES RELATING TO USE OF
26 HOSPITAL LIFETIME RESERVE DAYS.—Not later than 1 year
27 after the date of the enactment of this Act, the Inspector Gen-
28 eral of the Department of Health and Human Services shall
29 submit a report to Congress on—

30 (1) the extent to which hospitals provide notice to
31 medicare beneficiaries in accordance with applicable re-
32 quirements before they use the 60 lifetime reserve days de-
33 scribed in section 1812(a)(1) of the Social Security Act (42
34 U.S.C. 1395d(a)(1)); and

35 (2) the appropriateness and feasibility of hospitals pro-
36 viding a notice to such beneficiaries before they completely
37 exhaust such lifetime reserve days.